

Horizontal constitutional rights as conflict of laws rules: How transnational pharmagroups manipulate scientific publications

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Summary: The term “publication bias” is used to describe the statistical distortion of data when pharma groups suppress or manipulate research data in scientific publications. The authors discuss the publication bias as a paradigmatic case in order to critically examine four central aspects of third party effect of constitutional rights, and to develop alternatives. (1) The third party effect has so far been configured in an individualist perspective only, as balancing individual constitutional rights of private actors against each other. However, in order to deal with massive structural conflicts within society, constitutional rights in private relations have to be reformulated in their collective-institutional dimension. (2) Instead of being limited to the protection against state-equivalent power in society, the third party effect must be widened and directed against all communication media with expansive tendencies. (3) Contextualising constitutional rights ought not to be limited to adapting these rights to the particularities of private law only. It must go further than this and take into account the particular normativities of autonomous social institutions that are at risk. (4) Instead of imposing duties to protect exclusively on state actors, third party effects must actually address the private actors who violate constitutional rights themselves and at the same time activate counter-forces within society.

The authors recommend trial registration as third party effect of academic freedom and the right to health. Publicly accessible registers are set up on a binding basis, which fully record studies from their inception in order to ensure transparency and inspection throughout the entire research process.

Keywords: Horizontal effect of constitutional rights, third party effect of human rights, freedom of science, right to health, publication bias, trial registration

“But where are the pictures of the people who drowned?”¹

I. Publication Bias: The manipulation of clinical studies in the pharmaceutical network

The “Edronax” case: In 1997 the anti-depressant EDRONAX, which was manufactured by the pharmaceutical company Pfizer and contained the ingredient

¹ The poet Diagoras of Melos poses this provocative question when a priest shows him the votive pictures of people who have been saved by prayer from shipwreck, as a proof of the existence of God. Diagoras was subsequently sentenced to death. Marcus Tullius Cicero (1896) *De natura deorum*, London: Methuen.

Reboxetine, was licensed in Germany and other EU countries, although an attempt to have the drug licensed in the USA had failed. In 2010 the British Medical Journal revealed (as was confirmed by later studies carried out by IQWiG) that less than two thirds of the studies actually carried out, specifically those with positive results, had been duly published by Pfizer, while no mention was made of those studies that showed that in comparison with placebos the drug was not only ineffective but also had harmful side effects.²

The BASF versus Dong case: Boots Pharmaceuticals (now the Knoll Pharmaceutical Company), a subsidiary of BASF, commissioned the research scientist Prof. Betty Dong of the University of California in San Francisco to investigate the effectiveness of Synthroid, the drug most frequently prescribed for thyroid in the USA, in return for an advance payment for the research in the amount of a quarter of a million dollars. In return, Dong had to sign a contract stating that she would not publish any negative study results without Knoll's agreement. In fact, Synthroid was found not to have any advantages in terms of its effectiveness by comparison with comparable and cheaper generic products. On the basis of the contractual clause, and by making defamatory statements concerning Dong and her scientific methods, Boots then prevented publication for seven years. As a result, by claiming that Synthroid was a superior product, the Group was able to further expand its market share. When the Wall Street Journal made the case public in 1996, BASF had to face class actions from approximately 5 million claimants for inadmissible suppression of the study, unfair competition practices, and violation of consumer protection regulations. The company ultimately agreed to a settlement.³

The "hormone replacement therapies" case: Alongside many other pharmaceutical companies which had been in competition with each other from as far back as the 1940s over the prevention of symptoms of menopause by hormone replacement therapies, Wyeth (now Pfizer) organised marketing campaigns well into the 1990s. Without any basis in terms of the results of solid scientific studies, Wyeth promoted the preventive effect of the treatments. Only when an external randomised study was carried out in 1998, with further follow up studies and a Women's Health Initiative in 2002, was the preventive effect refuted and evidence produced concerning the health risks to women who had used these treatments, and who had developed breast cancer, stroke, thrombosis, dementia and incontinence more frequently after receiving the treatment. Media such as PLOS and the New York Times obtained court decisions forcing the disclosure of the marketing documents by the manufacturer Wyeth, in parallel with the compensation claims filed by the women whose health had been damaged. In the course of all this it emerged that the majority of the scientific articles on which the marketing campaign was based had been written in cooperation with communications agencies and ghost-writers.⁴

² Dirk Eyding, *et al.* (2010) "Reboxetine for a Cute Treatment of Major Depression: Sytematic Review and Meta-Analysis of Published and Unpublished Placebo and Selective Serotonin Reuptake Inhibitor Controlled Trials", *BMJ*, c4737; Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (2011) "Bupropion, Mirtazapin und Reboxetin zur Behandlung der Depression - A05-20C-Abschlussbericht", https://www.iqwig.de/de/projekte_ergebnisse/projekte/arsneimittelbewertung/a05_20c_bupropion_mirtazapin_und_reboxetin_zur_behandlung_der_depression.1132.html#berichte.

³ Cf. United States Court of Appeals, 7th Cir. (2008) *BASF AG v. Great American Assurance Co.*, 522 F.3d 813, 816. See Sheldon Krinsky (2003) *Science in the Public Interest: Has the Lure of Profits Corrupted Biomedical Research?*, New York: Rowman & Littlefield Publishers.

⁴ Adriane J. Fugh-Berman (2010) "The Haunting of Medical Journals: How Ghostwriting Sold "HRT"", *7 PLoS Medicine*, e1000335.

There is a long list of such scandals involving the big pharmaceutical companies. Over and over again, scientific findings concerning the harmful consequences of medicinal products for health, or the total absence of any consequences whatsoever for health, are not reaching the public, or only on a selective basis. These manipulations take many different forms, including selective publication,⁵ censorship clauses in research contracts, the use of ghost-writers, the application of pressure on researchers to prevent studies being carried out⁶, and even the dismissal of researchers by financially dependent research institutions.⁷ Underlying these cases is a conflict of incompatible rationalities⁸ that ultimately leads to a *publication bias*.⁹ This term is used to describe the statistical distortion of data when research data are suppressed or manipulated in scientific publications. It is not just a few regrettable isolated cases giving rise to concern because they create scandals in scientific research and healthcare. Numerous empirical studies have shown that *publication bias* is a worldwide problem, which is due to the massive conflicts of interest that exist between research institutions, the pharmaceutical industry, the healthcare system, the publishing world, investors and political regulation bodies. For example, a study, which compared protocols and subsequently published articles in 102 studies of medicinal products showed that in 62% of cases the published article seriously deviated from the study protocol.¹⁰ In a steadily increasing number of cases, negative (i.e. unwelcome) study results, which will not be effective in terms of the marketing of the substances concerned are withheld or manipulated, and only the positive results are published in the specialist journals. Thus, only a portion of the clinical studies carried out reach the public domain. These drastic selections are due to the massive interest of the pharmaceutical industry in positive clinical results, because these will exert a positive

⁵ Cf. also the criticisms made in the case of the Vioxx study (involving Merck as manufacturer), in which the myocardial infarction risk was concealed (Claire Bombardier, *et al.* (2000) "Comparison of Upper Gastrointestinal Toxicity of Rofecoxib and Naproxen in Patients with Rheumatoid Arthritis. VIGOR Study Group", 343 *The New England Journal of Medicine*, 1520-1528) and in the case of the study on the licensed swine flu drug Tamiflu, manufactured by Roche (Tom Jefferson, *et al.* (2012) "Neuraminidase Inhibitors for Preventing and Treating Influenza in Healthy Adults and Children", *Cochrane Database of Systematic Reviews*, Art. No.: CD008965).

⁶ See the case of the so called MIDAS study of the efficacy of calcium blockers (involving Sandoz, subsequently Novartis as manufacturer), in which the researchers successfully defended themselves. William B. Applegate, *et al.* (1996) "The Multicenter Isradipine Diuretic Atherosclerosis Study (Midas)", 277 *Journal of the American Medical Association*, 297-298.

⁷ For example, the dismissal of the research scientist Nancy Olivieri from the University of Toronto when she wanted to issue warnings about negative study results; her employer was receiving research grants from Apotex, the manufacturer of the drug under investigation. See A.M. Viens and Julian Savulescu (2004) "Introduction to The Olivieri Symposium", 30 *Journal of medical ethics*, 1-7.

⁸ For conflicts between incompatible rationalities in modern society, Max Weber (1968) *Gesammelte Aufsätze zur Wissenschaftslehre*, Tübingen: Mohr Siebeck, 3rd ed., 605ff.; Niklas Luhmann (2013) *Theory of Society*, Stanford: Stanford University Press, Vol. 2, Chap. 5.18.

⁹ See the early use of this term by M.L. Smith (1980) "Publication bias and Meta-analysis", 4 *Evaluation in Education*, 22-24.

¹⁰ An-Wen Chan, *et al.* (2004) "Empirical Evidence for Selective Reporting of Outcomes in Randomized Trials: Comparison of Protocols to Published Articles", 291 *Journal of the American Medical Association*, 2457-2465. A German study, Gisela Schott, *et al.* (2010) "Finanzierung von Arzneimittelstudien durch pharmazeutische Unternehmen und die Folgen; Teil1: qualitative systematische Literaturübersicht zum Einfluss auf Studienergebnisse -protokoll und qualität", 107 *Deutsches Ärzteblatt international*, 279-285; idem (2010) "Finanzierung von Arzneimittelstudien durch pharmazeutische Unternehmen und die Folgen; Teil2: qualitative systematische Literaturübersicht zum Einfluss auf Autorenschaft, Zugang zu Studiendaten sowie -registrierung und Publikation", 107 *Deutsches Ärzteblatt international*, 295-301.

influence on licensing and marketing. By financing research, the pharmaceutical industry tries to satisfy this need, employing more or less subtle means to intervene in scientific research. These manipulations are damaging not only to scientific research but also to the provision of healthcare generally.

It is not sufficient to describe *publication bias* as a consequence of individual corruption, which can be controlled by the regulatory bodies of national governments. In light of the worldwide activities of the big pharmaceutical companies and the globalisation of academic research, this is a conflict with transnational dimensions.¹¹ At the same time it points to a structural conflict within society, which political control will only be able to correct in isolated cases, without effectively getting to grips with the problem. Underlying the circumstances of the individual cases is a problem of constitutional rights – the conflict between different social rationalities.

II. Third party effect of constitutional rights: a critique and some alternatives

Can constitutional rights be used as conflict of laws rules to overcome this multidimensional conflict, which is being played out both in a national and a transnational context? Obviously there is a massive clash here between the interest of transnational pharmaceutical groups in the successful marketing of their products and the interests of the research community in publishing their results without hindrance, as well as the interest of the patients in having effective health protection. Of legal relevance here is the third party effect of constitutional rights, according to which actors can assert their constitutional rights (academic freedom and the right to health being the relevant rights here) not only vis-à-vis governmental bodies but also vis-à-vis private actors.¹² The term “third party effect” implies a transfer of constitutional rights in public law to relationships under private law. A central concern in this transfer is that the principles of private law are not violated in the process. For this reason a direct third party effect is usually rejected, and only an indirect third party effect is accepted, whereby the value system of constitutional rights is transformed by the general clauses of private law, and addressed to the judiciary. In parallel with this, the doctrine of protective duties establishes a responsibility of the legislator in regard to constitutional rights in private relationships. In essence, all third party effect concepts envisage a balancing of the private law subjects’ opposing rights taking place on the basis of the individual case.

By comparison with the longstanding tradition of constitutional rights, which was based exclusively on the relationship between the individual and the state, the third party effect represents a significant change. It responds to the emergence of

¹¹ Adriana Petryna (2009) *When Experiments Travel: Clinical Trials and the Global Search for Human Subjects*, Princeton: Princeton University Press.

¹² For the current discussion in Germany, Wolfgang Rübner (2011) "Grundrechtsadressaten", in: Josef Isensee and Paul Kirchhof (ed) *Handbuch des Staatsrechts der Bundesrepublik Deutschland*, Heidelberg: C.F. Müller, Rn. 83-125; in a historical perspective Michael Stolleis (2012) *Geschichte des öffentlichen Rechts in Deutschland IV*, München: C.H. Beck, 216ff. On the legal position in Europe, Andrew Clapham (2006) *Human Rights Obligations of Non-State Actors*, Oxford: Oxford University Press. For international law, Stephen Gardbaum (2003) "The 'Horizontal Effect' of Constitutional Rights", 102 *Michigan Law Review*, 387-459; John Ruggie (7 April 2008) "Protect, Respect, and Remedy: A Framework for Business and Human Rights, Report of the Special Representative of the Secretary-General on Human Rights and Transnational Corporations and Other Business Enterprises, A/HRC/8/5", 6-13. On academic freedom, Eberhard Schmidt-Aßmann (2000) "Wissenschaftsplanung im Wandel", in: Wilfried Erbguth, et al. (ed) *Planung. Festschrift für Werner Hoppe zum 70. Geburtstag*, München: C.H. Beck, 649-665, 653.

intermediary social forces with the transfer of public law norms into private law relationships. Yet it is precisely in the image of a transfer that the problem lies. The differences between the sender's context and the recipient's context are so great as to make any transfer of norms in the strict sense impossible. Instead, what is needed is a separate re-construction of constitutional rights which is dependent on the recipient's context. The transfer metaphor may still be convincing as a kind of transitional semantic, whereby constitutional rights asserted against the state are "transferred" to private law and acquire "third party effect" vis-à-vis social actors. In the long term, however, constitutional rights within society can only be understood on the basis of their different origin of intra-societal conflicts. Intra-societal conflicts are fundamentally different from state-society conflicts. They differ in the circumstances of the constitutional right violation and in their appropriate sanctions, so that the simple term "third party effect" of constitutional rights originally asserted against the state is misleading.

The challenge consists in releasing the third party effects in private law from their clandestine attachment to the state, and developing their standards from the outset on the basis of intra-societal conflicts. In the following, therefore, we discuss *publication bias* as a paradigmatic case in order to critically examine four central aspects of third party effect theory, and to develop alternatives.

Theses:

1. The third party effect has so far been configured in an individualist perspective only, as balancing individual constitutional rights of private actors against each other. However, in order to deal with massive structural conflicts within society, constitutional rights in private relations have to be reformulated in their collective-institutional dimension.

2. Instead of being limited to the protection against state-equivalent power in society, the third party effect must be widened and directed against all communication media with expansive tendencies.

3. Contextualising constitutional rights ought not to be limited to adapting these rights to the particularities of private law only. It must go further than this and take into account the particular normativities of autonomous social institutions that are at risk.

4. Instead of imposing duties to protect exclusively on state actors, third party effects must actually address the private actors who violate constitutional rights themselves and at the same time activate counter-forces within society.

1. Constitutional rights as collective institutions

An initial critique is directed against the prevailing understanding of the third party effect as a balancing of individual constitutional rights.¹³ If the third party effect is seen as a transfer of public constitutional rights into private relationships, this ignores

¹³ Karl-Heinz Ladeur (2004) *Kritik der Abwägung in der Grundrechtsdogmatik*, Tübingen: Mohr Siebeck; Andreas Fischer-Lescano (2008) "Kritik der praktischen Konkordanz", 2 *Kritische Justiz*, 166-177. A critique of the legal situation in the USA, Jud Mathews and Alec Stone Sweet (2011) "All Things in Proportion? American Rights Review and the Problem of Balancing", 4 *Emory Law Journal*, 102-179, 116.

the fact that a mere transfer will alter the structure of the rights and reduce legal protection. The question of the possible unlawfulness of any interference is not examined; instead, legal subjects under private law are classified as “violators” and “violated” and their equally justified constitutional right positions are brought into “practical concordance” in the individual case.¹⁴ This does not provide more than a purely formal additional value by comparison with the protection of subjective rights in tort law. On the contrary, the legal protection is reduced, since violations of constitutional rights are much more difficult to establish, the balancing dimensions multiply, and the political leeway for balancing expands.¹⁵ And making the decision concerning violations of constitutional rights dependent on the circumstances of the individual case makes it impossible to formulate general norms for such far-reaching issues. This amounts to a level of casuistry that is conceptually uncontrollable.

However, the most important objection to such an exclusive focusing on individual rights is that we fail to address the central problem of violations of constitutional rights within society. While it has long been recognised in public law that constitutional rights serve to protect both individual rights and social institutions¹⁶, the third party effect in private law has so far generally only focused on individual protection and has neglected the protection of institutions. The Federal Constitutional Court [BVerfG] regards the conflict here as only between individual subjective rights of “equal-ranking holders of constitutional rights”, between “conflicting constitutional right positions” “in their interdependency”.¹⁷ And their private law critics respond at the same level, i.e. the level of individual rights.¹⁸ In so doing, both ignore the fact that here the collective-institutional dimension of constitutional rights becomes virulent.

In the conflict between collective institutions, however, lies the really controversial problem of the third party effect. The term “collective-institutional” distances itself against Carl Schmitt’s institutionalism and refers explicitly to Helmut Ridder’s theory of “non personal constitutional rights”, according to which “constitutional rights are aimed at the specific freedom of a social field through the organisation of that field” – freedom of science or freedom of art, for example.¹⁹ It should in particular be emphasised in that in contrast to politically conservative preconceptions, “institution” is understood not as a legal guarantee for the permanent

¹⁴ The principle is defined by Konrad Hesse (1999) *Grundzüge des Verfassungsrechts der Bundesrepublik Deutschland*, Heidelberg: C.F. Müller, 4th ed., Rn. 72.; Robert Alexy (2002) “Verfassungsrecht und einfaches Recht – Verfassungsgerichtsbarkeit und Fachgerichtsbarkeit”, 61 *VVdStRL*, 7ff. Early on, BVerfG, BVerfGE 83,130 – Mutzenbacher.

¹⁵ For a critical view on state duties of care in the “risk society” see Ralph Christensen and Andreas Fischer-Lescano (2007) *Das Ganze des Rechts. Vom hierarchischen zum reflexiven Verständnis deutscher und europäischer Grundrechte*, Berlin: Duncker & Humblot, 311ff.

¹⁶ In general Horst Dreier (1993) *Dimensionen der Grundrechte. Von der Wertordnungsjudikatur zu den objektiv-rechtlichen Grundrechtsgehalten*, Hannover: Hennies & Zinkeisen, 27 ff.

¹⁷ BVerfGE 89, 214 – Bürgschaft.

¹⁸ Wolfgang Zöllner (1996) “Regelungsspielräume im Schuldvertragsrecht: Bemerkungen zur Grundrechtsanwendung im Privatrecht und zu den sogenannten Ungleichgewichtslagen”, 196 *Archiv für die civilistische Praxis*, 1-36.

¹⁹ Helmut Ridder (1975) *Die soziale Ordnung des Grundgesetzes*, Opladen: Westdeutscher Verlag, 90 f.; idem (1963) *Die Freiheit der Kunst nach dem Grundgesetz*, Berlin: Vahlen. A concise definition of the term by Fabian Steinhauer (2013) “Das Grundrecht der Kunstfreiheit: Kommentar zu einem Grundlagentext von Helmut Ridder”, *Manuskript Frankfurt*, Steinhauer introduces the term “collective-institutional” and uses it to describe Ridder’s constitutional rights theory in contradistinction to Carl Schmitt’s “institutional” constitutional rights theory.

existence of social structures against tendencies of political change – in Carl Schmitt's definition: "what is present, formally and organisationally exists and is at hand"²⁰ -, but as a socio-legal normativization process which is subject to constant change.

Admittedly it is entirely possible, in the case of *publication bias*, for scientists to assert individual defence claims against the censorship imposed by the big pharmaceutical companies, or to plead the nullity of contracts that prevent publication, or for patients to sue for damages. But all of private litigation by individual actors fails to take account of the collective-institutional dimension, and therefore also the really difficult conflicts within society. For the manipulations of the big pharmaceutical companies do not merely violate individual rights of scientists and patients, but also – and in a more profound way – the integrity of social institutions, scientific research and the provision of healthcare.²¹

It needs to be stressed that the collective-institutional dimension plays a part not only for the victims of the rights violations but on both sides of the horizontal constitutional rights relationship. If the victim side includes institutions as well as individuals, then on the perpetrators side it is not only persons, but also anonymous social processes that in some cases must be held responsible for the violation of constitutional rights. This two-sided aspect of the collective-institutional relationship is often overlooked. However, the discussion in criminal law, concerning the so-called macro-criminality and the criminality of formal organisations, which has as its background the sociological debate on "structural violence",²² has developed such a collective-institutional perspective for the perpetrators' side also.

In such cases, violations of constitutional rights are ultimately attributable to non-personal social processes, which use human actors as their agents.²³ Structural violence refers to an "anonymous matrix", i.e. not only "collective actors" which tend to be more visible (states, political parties, commercial companies, groups of companies, associations), but as well (with an equal if not greater intensity) anonymous communicative processes (institutions, functional systems, networks), which are difficult to address because they are definitely not personified as collective actors.²⁴ The hazards that emanate from the digital processes of the Internet are a

²⁰ Carl Schmitt (1985 (1931)) "Freiheitsrechte und institutionelle Garantien der Reichsverfassung", in: Carl Schmitt (ed) *Verfassungsrechtliche Aufsätze aus den Jahren 1924-1954*, Berlin: 140-178, 155.

²¹ The fact that academic freedom is put at risk not only through governmental interference but also by social (in particular, industrial) influences, and accordingly requires effective protection of its constitutional rights, is emphasised by Ino Augsberg (2012) "Subjektive und objektive Dimensionen der Wissenschaftsfreiheit.", in: Friedemann Voigt (ed) *Freiheit der Wissenschaft. Beiträge zu ihrer Bedeutung, Normativität und Funktion*, Berlin: De Gruyter, 65-89, 74.

²² *Locus classicus* on structural violence, Johan Galtung (1965) "Institutionalized Conflict Resolution: A Theoretical Paradigm", 2 *Journal of Peace Research*, 348-397; on macro-criminality, Herbert Jäger (1989) *Makrocriminalität: Studien zur Kriminologie kollektiver Gewalt*, Frankfurt: Suhrkamp.

²³ For clarity it should be stressed that this does not mean that individual responsibility is eclipsed by collective responsibility, but rather that both exist side by side at all times, although they are subject to different preconditions.

²⁴ More details in Gunther Teubner (2006) "The Anonymous Matrix: Human Rights Violations by 'Private' Transnational Actors", 69 *Modern Law Review*, 327-346. Steinhauer (fn 19) 4 stresses, too, that the collective-institutional dimension is not properly grasped if the term refers only to legal entities and collective actors. For an institutional interpretation of the horizontal effect of constitutional rights in the transnational arena, Lars Viellechner (2013) *Transnationalisierung des Rechts*, Weilerswist: Velbrück, 217 ff.

particularly clear example.²⁵ At the centre of the conflict is the clash between irreconcilable rationalities: action, which is economically rational, has a structurally corrupting effect on the particular rationalities of scientific activities and of the healthcare system. And a particular feature of the clash is its asymmetry. Constitutional rights have to be protected in such asymmetrical situations, in which the expanding economic dynamic weakens the fragile internal functioning mechanisms of scientific research and healthcare.

*Constitutional rights as a collective institution – this means, therefore, a two-sided relationship in which guarantees of autonomy are given to social processes to prevent them from being overwhelmed by the totalising tendencies of other social processes.*²⁶ In this collective-institutional dimension, constitutional rights function as conflict of laws rules, which operate within the conflict between the opposing rationalities of different parts of society. They seek to protect the integrity of art, of the family, and of religion in the face of the totalising tendencies at work in society, i.e. technology, the media and the economy. It is obvious that we will not advance any further in this context if we try to balance individual constitutional rights against each other.

Instead, the horizontal protection of constitutional rights must be consistently transmuted into organisation and process. Institutional protection for areas of social autonomy have been implemented for some time in public law, particularly in media law.²⁷ In the field of the mass media, freedom of opinion cannot be effectively protected by means of subjective rights for individual actors, but only through organisation and process.²⁸ This insight needs to be applied more generally, particularly in regard to the horizontal effect of constitutional rights in different social areas.

Of special relevance is the contextual adequacy of any such collective-institutional protection of constitutional rights. Organisation and process must be selected in such a way as to be oriented to the specific contexts on both sides of the violation – the violators as much as the violated.²⁹ In the case of *publication bias*, the guiding question is therefore: under what conditions is the economic exploitation of research results intrusive in such a way that it violates the core area of the integrity of research, on the one hand, and that of healthcare on the other? Criteria need then to be formulated in two different directions: (1) What constitutes the specific risk potential of economic processes that violate constitutional rights, when pressure is applied on the publication of research results? (2) How, in this connection, are we to define the core area of scientific research and the healthcare system which needs to

²⁵ Cf. Byung-Chul Han (2014) "Im digitalen Panoptikum: Wir fühlen uns frei. Aber wir sind es nicht. ", 2 *Der Spiegel*, 106.

²⁶ This formulation goes beyond Luhmann's concept of constitutional rights insofar as it deals not only with the totalising tendencies of politics, but also those of other systems, Niklas Luhmann (1965) *Grundrechte als Institution: Ein Beitrag zur politischen Soziologie*, Berlin: Duncker & Humblot.

²⁷ BVerfGE 57, 295, 320 – 3. Rundfunkentscheidung.

²⁸ Thomas Vesting (2013) "Die Tagesschau-App und die Notwendigkeit der Schaffung eines „Intermedienkollisionsrechts“, in: Indra Spiecker (ed) *Karlsruher Dialog zum Informationsrecht*, Karlsruhe: KIT Scientific Publishing, 1ff.; Karl-Heinz Ladeur (2007) *Das Medienrecht und die Ökonomie der Aufmerksamkeit. In Sachen Dieter Bohlen, Maxim Biller, Caroline von Monaco u.a.*, Köln: Halem, 255ff., 268ff.

²⁹ For details, Gunther Teubner (2012) *Constitutional Fragments: Societal Constitutionalism and Globalization*, Oxford: Oxford University Press, 142ff.

protected against the manipulation of results? Only when these two questions have been answered with sufficient accuracy can we determine how organisation and process have to be structured so that the violated integrity of scientific research and the healthcare system can be restored

2. Expansionary tendencies of the communication media

A second weak point of traditional third party effect doctrines is that they concentrate exclusively on protection from social power.³⁰ This is made particularly clear by the US American *state action* doctrine.³¹ A third party effect of constitutional rights is established, if socio-economic power equivalent to state power emanates from private actors.³² But also the third party effect theory, which prevails in Germany links up with structural imbalances and hazards, and only takes social power phenomena into consideration.

Indisputably, legal protection in the face of socio-economic power is an important area of the third party effect, but here, too, the weakness of the transfer principle is noticeable. For only if the issue were to transfer state-directed constitutional rights to intra-societal conflicts then would it be plausible to restrict constitutional rights to cases in which private power of an intensity comparable to state power has arisen in society. For this reason the third party effect has been successful in labour law, since private property is transformed here into organisational power of the *private government*, which in terms of its impact is in no way inferior to the exercise of state power.³³

Yet if we focus exclusively on socio-economic power we fail to see other, subtler causes of constitutional rights violations. Although it is appropriate for constitutional rights to be aimed against power phenomena in the state sphere, it is not appropriate to limit constitutional rights to the communication medium of power, if constitutional rights violations occur within society. In principle, constitutional rights are put at risk not only from power, but from all communicative media as soon as autonomous subsystems develop expansionary dynamics. In today's world, that means primarily the expansionary tendencies of the economy, technology, medicine and (of particular relevance at the present time) the information media. Social power is thus only a partial phenomenon of the social risks to which constitutional rights are exposed. The main differences between social and political constitutional rights are the result of the respective internal reproduction conditions of the affected sphere of society. In politics, constitutional rights are primarily directed against the dangers of power. In other social systems, constitutional rights are directed against risks emanating from the specific communication media for the social system in question,

³⁰ A survey in Jürgen Schwabe (1971) *Die sogenannte Drittwirkung der Grundrechte. Zur Einwirkung der Grundrechte auf den Privatrechtsverkehr*, München: Goldmann, 12ff.

³¹ Cf. US Supreme Court (1883), Civil Rights Cases, 109 US 3. Kritisch dazu, Stephen Gardbaum (2003) "The 'Horizontal Effect' of Constitutional Rights", 102 *Michigan Law Review*, 387-459.

³² Andrew Clapham (2006) *Human Rights Obligations of Non-State Actors*, Oxford: Oxford University Press; Karsten Nowrot (2007) "Den „Kinderschuhen“ entwachsen: Die (Wieder-) Entdeckung der rechtssoziologischen Perspektive in der Dogmatik der Völkerrechtssubjektivität", 28 *Zeitschrift für Rechtssoziologie*, 21-48.

³³ Franz Gamillscheg (1964) "Die Grundrechte im Arbeitsrecht", 164 *Archiv für die civilistische Praxis*, 385-445; Dieter Conrad (1965) *Freiheitsrechte und Arbeitsverfassung, 1965*, Berlin: Duncker & Humblot.

i.e. from monetary operations in the economy, from cognitive-technical operations in science and technology, and from information flows in the media system.³⁴

In the case of publication bias, power certainly plays an important role. In particular, the censorship contracts forced on scientists by the pharmaceutical industry indicate an asymmetric power distribution. Yet we ought not to focus solely on the power phenomenon. We must also take action against the subtler ways in which economic influence is exerted, which – without any manifest exercise of power – “substitute extra-scientific values and standards for intra-scientific relevance”.³⁵ In particular, we must take into consideration the corruptive influence of payment flows, above all when these are not transformed into organisational or contractual power. The technique of influence exercised by the pharmaceutical companies is not “prohibitive or repressive, but seductive ... it leads its victims astray rather than telling them what they must not do.”³⁶ Its motivating force is based not on the power of negative sanctions, but on the vast financing requirements of scientific research, towards which the seductive techniques of the pharmaceutical companies are directed with pinpoint accuracy. “Because research is so intensive in terms of staff and resources, the financing of scientific activity is the ‘nerve centre’ of its freedom.”³⁷ This is another reason why, if constitutional rights are merely structured as defensive rights against power, they are only able to achieve a limited amount against the influences exerted by the money medium. Effective protection from these seductive techniques thus becomes the challenge that has to be addressed by the third party effect concept.³⁸

Of course, not every economic influence, which is brought to bear on scientific research, is necessarily a violation of constitutional rights. The contact between science and industry takes many different forms, including marketing of scientific results, influence over the choice of research topics as a result of companies sitting on university supervisory committees, the financing of profitable projects, the practice of industrial research, applied research generally, and the close cooperation between industry and science in Silicon Valley contexts.³⁹ All of these may give rise to political regulations, but as long as the core autonomy of science is not affected they do not constitute a violation of constitutional rights.

It is only when the external influences systematically manipulate the scientific code itself, i.e. seek to determine from outside what is true and what is false – as in the case of the politically inspired theories of Lysenko in the Soviet Union – that the

³⁴ As emphasized by Gert Verschraegen (2013) "Differentiation and Inclusion: A Neglected Sociological Approach to Fundamental Rights ", in: Mikael Rask Madsen and Gert Verschraegen (ed) *Making Human Rights Intelligible: Towards a Sociology of Human Rights*, Oxford: Hart, 25-60.

³⁵ Rudolf Stichweh (1994) *Wissenschaft, Universität, Professionen*, Frankfurt: Suhrkamp, 28

³⁶ The formulations which were coined for digital manipulation apply equally to manipulation in the context of publication bias, Byung-Chul Han (2014) "Im digitalen Panoptikum: Wir fühlen uns frei. Aber wir sind es nicht. ", 2 *Der Spiegel*, . Whether this should be referred to in terms of “power technique”, as currently often occurs under the Foucault’s influence, is doubtful, because in this case the medium of communication is not power but money, and constitutional rights risks arise without the translation of money into power.

³⁷ Eberhard Schmidt-Aßmann (2000) "Wissenschaftsplanung im Wandel", in: Wilfried Erbguth, *et al.* (ed) *Planung. Festschrift für Werner Hoppe zum 70. Geburtstag*, München: C.H. Beck, 649-665, 657.

³⁸ See section 3 Contextualisation for further detail on this point.

³⁹ On commercialisation of science, Christian Bumke (2009) "Universitäten im Wettbewerb", 69 *Veröffentlichungen der Vereinigung der Deutschen Staatsrechtslehrer*, 407-461.

core area of scientific research is violated.⁴⁰ When economic rational choice usurps the role of scientific rationality, when it replaces the scientific code with the economic code, the violation of academic freedom is obvious. But this is precisely what does not normally happen in the context of publication bias. The pharmaceutical industry is wary of directly interfering in research processes and telling scientists what results they are to produce.⁴¹ Any such crude external interference in the binary code of scientific research or its programmes would – as the Lysenko disaster demonstrated – be regarded as risible in light of the established practice of scientific research. The manipulation in question here is very much subtler and therefore more dangerous, because the way in which it becomes inscribed into the research process itself and gives rise to publication bias is almost imperceptible.⁴² Evidence is therefore also extremely difficult to obtain. Only time-consuming empirical and statistical research (as described at the beginning of this paper) is able to finally prove the systematic falsification of the publication process.

This makes it even more difficult to determine precisely in such situations how scientific autonomy is being put at risk. The thesis being pursued here is as follows: *The reason, why the manipulations encroach on the core area of science is not that they directly violate the binary code of science or its programmes, methods and theories. Rather, they interfere with the evolution of science insofar as they systematically falsify the fragile selection mechanism.* The precarious interconnections between variation, selection and retention of scientific evolution are exposed to the economically motivated manipulations of the publication mechanism. This has dramatic consequences as far as the autonomy of the scientific system is concerned. At the same time, in the interplay of social autonomous areas, the economic infiltration of science violates the integrity of the healthcare system..

(1) Violation of the publication mechanism

With publication, the evolution of the science system has developed a selection mechanism,⁴³ which selects system-relevant results from among the variations of ongoing research activity. Initial publication in relevant specialist journals has the function of filtering out, from among the many different variations of the internal research process, the results that will determine the direction of further development. By making new knowledge visible, publication makes a selection from among the variations of the scientific process, which are running via the binary code and the programmes, and makes it possible for research results to be stabilised as the “status of knowledge” in educational literature and manuals; this stabilisation

⁴⁰ See Shores A. Medwedjew (1971) *Der Fall Lyssenko. Eine Wissenschaft kapituliert*, Hamburg: Hoffmann & Campe.

⁴¹ Admittedly this does not always apply. In many cases industry (which depends upon market innovations) attempts to directly control the actual scientific output and even to cause scientists to openly falsify the allocation of the values of the science code.

⁴² According to Niklas Luhmann, massive external pressure on the scientific research system leads to an inflation of the truth medium. “Much value is placed [...] on commitments to truth, without any adequate guarantee that these commitments can be fulfilled. Chances of internal integration, empirical verification, and the accuracy of concepts are neglected in order to meet the widespread interest in research results. Like a fever, inflationary phenomena of this kind are a clear symptom that the system is defending itself against external influences by accommodating them.” Niklas Luhmann (1990) *Die Wissenschaft der Gesellschaft*, Frankfurt: Suhrkamp, 623.

⁴³ See Luhmann (fn 42) 576ff.; Rudolf Stichweh (2007) “Einheit und Differenz im Wissenschaftssystem der Moderne”, in: Jost Halfmann and Johannes Rohbeck (ed) *Zwei Kulturen der Wissenschaft - revisited*, Weilerswist: Velbrück, 213-228.

stimulates new variations in its turn.⁴⁴The practice of publication establishes scientific objectivity and impartiality, because it makes it possible for scientific findings to be verified according to the criteria of integration into other areas of research and openness to criticism.⁴⁵Thus the social institution of the functioning practice of publication is just as much part of the protection of scientific freedom as is the principle of freedom of publication itself. Here we can see the interplay between the individual and the collective-institutional levels of constitutional rights. Constitutional rights relate not only to individuals but also to “collective institutions ... which cannot be seen as a counterpart to the subject, because they are involved in the (re) production of the subject, without being a macro-subject.”⁴⁶Individual constitutional rights are not limited by collective institutions, but function as the space in which collective institutions are realised.⁴⁷Conversely, enforceable individual constitutional rights have an advocacy function in regard to the protection and further development of collective institutions.

Economically motivated manipulation impairs this mechanism both directly and indirectly. In the direct sense, the contractual rights of disposal and exploitation and censorship clauses imposed by the pharmaceutical networks may not intervene in the “production” of scientific results, but they certainly intervene in their “presentation”.⁴⁸ Negative studies are withheld and study results are manipulated so that the population of publication records is increased in the direction of profitable results, i.e. the frequency distribution of positive and negative research results is significantly shifted in favour of the positive results.

By contrast, indirect impairment occurs if financing pressure is brought to bear on the scientific world’s internal interest in its research findings. In that case the publication of positive study results is more lucrative and more interesting for the researchers than the publication of negative study results.⁴⁹ “Good scientific practice” as an internal criterion for behaviour among scientists, which would have regarded any such selective publication as scientific misconduct, becomes less relevant.⁵⁰ An

⁴⁴ Concerning the complex relationship between variation, selection and stabilisation in the evolution of science, Luhmann (fn 42) 583, 587f.

⁴⁵ On the “communicative constitutional right” of academic freedom, e.g. Sophie-Charlotte Lenski (2007) *Personenbezogene Massenkommunikation als verfassungsrechtliches Problem: Das allgemeine Persönlichkeitsrecht in Konflikt mit Medien, Kunst und Wissenschaft*, Berlin: Duncker & Humblot. But see also, Eberhard Schmidt-Aßmann (2005) "Wissenschaft – Öffentlichkeit – Recht", in: Horst Dreier (ed) *Rechts- und staatsrechtliche Schlüsselbegriffe: Legitimität – Repräsentation – Freiheit, Symposium für Hasso Hofmann zum 70. Geburtstag*, Berlin: Duncker & Humblot, 67ff.

⁴⁶ Steinhauer (fn 19) 4.

⁴⁷ On the institutional dimension of academic freedom, for example BVerfGE 35, 79, 112; Ino Augsberg, (fn 21), 77-80.

⁴⁸ See Helga Nowotny (2005) "The Changing Nature of Public Science", in: Helga Nowotny (ed) *The Public Nature of Science under Assault. Politics, Markets, Science and the Law*, Berlin-Heidelberg: Springer, 1-28; Joel Lexchin, et al. (2003) "Pharmaceutical Industry Sponsorship and Research Outcome and Quality: Systematic Review", 326 *BMJ*, 1167-1177.

⁴⁹ Philippa J. Easterbrook, et al. (1991) "Publication Bias in Clinical Research", 337 *The Lancet*, 867-872; Kay Dickersin, et al. (1992) "Factors Influencing Publication of Research Results. Followup of Applications Submitted to two Institutional Review Boards", 267 *Journal of the American Medical Association*, 374-378.

⁵⁰ Cf. Daniele Fanelli (2010) "Do Pressures to Publish Increase Scientists' Bias? An Empirical Support from US States Data", 5 *PLoS ONE*, 1-7; Kay Dickersin (1990) "The Existence of Publication Bias and Risk Factors for its Occurrence", 263 *Journal of the American Medical Association*, 1385-1389; Lesli Gelling (2013) "Negative Results have a value", 20 *Nurse Researcher*, 3. For a *time-lag bias*, Jerome Stern and R. John Simes (1997) "Publication Bias: Evidence of Delayed Publication in a Cohort Study

imperceptible change thus takes place in the way in which the scientific world itself understands what the purpose of publication is. Symptomatic of this development is the increasing and barely transparent use of so called communications agencies and ghost-writers. Prominent researchers seeking to enhance their reputations are falsely named as the authors of studies, which have actually been written by anonymous ghost-writers, consultancy companies or employees of the big pharmaceutical companies.⁵¹

Some publishing houses also encourage such manipulations by adapting their publication methods to the expectations of the big pharmaceutical companies and the financial pressures imposed by them, and accepting mainly positive results.⁵² Not infrequently, agreements are reached between widely circulated medical publishing houses and the big pharmaceutical companies, who co-finance the publishing houses through drugs advertising. Agreements are reached in regard to both the orientation of the specialist journal and the publication criteria.⁵³ In addition there is the problem of finding independent experts to carry out peer reviews in the pharmaceutical sphere, to ensure that conflicts of interest, which may influence the results, can be avoided.

If economic interests influence the practice of scientific publication in this way, the internal selection criteria by which scientists operate will be replaced by criteria, which have nothing to do with science. Peer review processes will be pointless, because negative data do not appear. The possibility of integration into subsequent and parallel research is put at risk, or worse still, the falsification is incorporated into subsequent research.⁵⁴ For if false data are used as a basis for follow-on research, this will ultimately affect the way in which the values of the "truth code" of science itself are allocated. The repercussions of publication bias for research practice tend to loosen the connection between research and publication. The core of scientific self-reproduction is put at risk.

(2) Violation of the healthcare system

At the same time, this practice violates the right to health, in both a collective-institutional and an individual sense. The collective institutions of politics and of the health system are dependent (as are doctors administering treatment) on full disclosure of all studies carried out in regard to a medical product. If findings on

of Clinical Research Projects", 315 *BMJ*, 640-645. Concerning the distorting effect of multiple publication, Martin R. Tramèr, *et al.* (1997) "Impact of Covert Duplicate Publication on Meta-analysis: a Case Study", 315 *BMJ*, 635-640.

⁵¹ The PLoS Medicine Editors, *et al.* (2011) "Ghostwriting Revisited: New Perspectives but Few Solutions in Sight", 8 *PLoS Medicine*, e1001084.

⁵² See Martina Franzen (2011) *Breaking News: Wissenschaftliche Zeitschriften im Kampf um Aufmerksamkeit*, Baden-Baden: Nomos, 73ff., 88ff.

⁵³ Cf. the study by Annette Becker and Fatma Dörter (2011) "The Association between a Journal's Source of Revenue and the Drug Recommendations Made in the Articles it Publishes", 183 *Canadian Medical Association Journal*, 544-548; see also, Aaron Kesselheim (2011) "Covert Pharmaceutical Promotion in Free Medical Journals", 183 *Canadian Medical Association Journal*, 534-535. For the independence initiative by the International Society of Drug Bulletins and WHO, Jörg Schaaber, *et al.* (2011) "Warum unabhängige Arzneimittelzeitschriften und Fortbildungsveranstaltungen wichtig sind", in: Klaus Lieb, *et al.* (ed) *Interessenskonflikte in der Medizin – Hintergründe und Lösungsmöglichkeiten*, Berlin, Heidelberg: Springer, 237ff., 244ff.

⁵⁴ See Ikhlaaq Ahmed, *et al.* (2012) "Assessment of Publication Bias, Selection Bias, and Unavailable Data in Meta-analyses Using Individual Participant Data: a Database Survey", 344 *BMJ*, d7762.

negative consequences for health are withheld or manipulated, the effects of substances cannot be objectively recorded because of the selective nature of the data in specialist journals. This leads to seriously wrong decisions being taken, because the positive effects are overestimated, in the context of both drug licensing and patient treatment.⁵⁵ Since according to §§ 21 ff. of the German Medical Products Act [AMG] clinical studies serve as a basis for drug licensing and the medical products regulatory authorities no longer investigate such products independently, this manipulation directly results in the efficacy and usefulness of drugs being incorrectly evaluated. The consequence, as the Edronax case demonstrates, is that incorrect efficacy information is provided in package inserts and incorrect reimbursement decisions are made by the health insurance funds. Treatment guidelines drawn up by specialist companies are incorrect. Statutory control bodies such as IQWiG and ethical commissions cannot fulfil their function, since they have to rely on defective data.⁵⁶

The risks to patients are obvious. The distortion of studies exposes patients to useless or even harmful treatments. Drugs, which are actually effective remain hidden from view and are withheld from patients. When studies that have already been carried out are concealed, test subjects unnecessarily undergo new studies.⁵⁷

3. Contextualisation

There is a third weak point of the traditional third party effect doctrine. It is also connected with the misapplied transfer principle. Since the third party effect is understood simply as the transfer of constitutional rights from public law to private law relations, due care needs to be exercised to ensure that the basic principles of private law are not violated. Accordingly, the theory of the indirect third party effect regards the adaptation to private law as best guaranteed if the constitutional rights are indirectly incorporated into private law through the general clauses. The theory of the duty of protection requires legislation to formulate standards that respect the principles of private law.

Of course, social constitutional rights need to be adequate to their context. But their context is definitely too narrowly understood if it is merely defined as the world of private law. The claim “of holding fast to the fundamental independence and autonomy of civil law vis-à-vis the system of constitutional rights under constitutional law”⁵⁸ only describes a first step of contextualisation. The second step places us before a much more difficult challenge: state-directed constitutional rights are to be modified not only according to the context of private law, but also according to the different contexts of society in which they are applied. They have to be newly calibrated in order to protect the particular rationality and normativity of each different area of society in which constitutional rights are at risk.⁵⁹

⁵⁵ Alison Tonks (2002) "A Clinical Trials Register for Europe", 325 *BMJ*, 1314-1315.

⁵⁶ An analysis of defective conclusions in Alexander Sutton, *et al.* (2000) "Empirical Assessment of Effect of Publication Bias on Meta-analysis", 320 *BMJ*, 1574-1577.

⁵⁷ Richard Horton (1997) "Medical Editors Trial Amnesty", 350 *The Lancet*, 756.

⁵⁸ Günter Dürig (1956) "Grundrechte und Zivilrechtsprechung", in: Theodor Maunz (ed) *Vom Bonner Grundgesetz zur gesamtdeutschen Verfassung: Festschrift Hans Nawiasky*, München: Isar, 157-210, 158f.

⁵⁹ Concerning the reformulation of constitutional rights in the business context, the classic study by Philip Selznick (1969) *Law, Society and Industrial Justice*, New York: Russell Sage, 75 ff., 259 ff.; more recently Jens Schierbeck (2000) "Operational Measures for Identifying and Implementing Human

This is where the transfer principle comes up against its limits. While in the it may be possible to transfer individual constitutional rights from public law into private law relationships, any transfer of institutional constitutional rights, i.e. a transfer of previously defined organisation and already established processes, is bound to fail because of the of particularities of the social fields involved.⁶⁰ Adequate protection of constitutional rights cannot be obtained via a uniform conception to be applied to all areas of society,⁶¹ it has to be ensured “on site” by careful and sensitive contextualisation.

The question of what organisation and what processes will protect constitutional rights of the collective institutions of scientific research and healthcare against the harm that can be done by economic action must be answered primarily via the normative self-understanding of the social practices that are at risk.⁶² In their codes and programmes, science and healthcare develop normative orientations, which are not the same as the commonly held opinions of individuals, instead having a collective-institutional character.⁶³ Such collective-institutional norms, which are rooted in structures, which have evolved historically, are discussed, criticised and reformulated in the reflective discourses of science and healthcare before the law examines them according to its own criteria and establishes new legal norms.

As far as publication bias is concerned, the reflective discourses of science and healthcare have in fact developed a collective-institutional alternative to individual protection, the implementation of which in law is to be recommended:⁶⁴ *trial registration as third party effect of academic freedom and the right to health through organisation and process.*⁶⁵ Publicly accessible registers of studies and results are set up on a binding basis, which fully record studies from their inception in order to ensure transparency and inspection throughout the entire research process.⁶⁶ This

Rights Issues in Corporate Operations", in: Asbjorn Eide, *et al.* (ed) *Human Rights and the Oil Industry* Antwerpen: Intersentia, 161-177, 168.

⁶⁰ Luhmann (fn 26) 188: The special nature of social spheres deserves protection against the levelling effect of politicisation.

⁶¹ Although this view is maintained on the basis of human dignity as the supreme constitutional principle of objective law, Günter Dürig (1957) in: Günter Dürig and Theodor Maunz (ed) *Grundgesetz. Kommentar*, München: C.H. Beck, Art.1 Rn. 5ff.

⁶² This corresponds to the practice of the German Constitutional Court (BVerfG), on the legal concept of science, art and other social spheres, which relies on their own self-understanding, BVerfGE 111, 333, 354; decision of 20.07.2010, case no. 1 BvR 748/06, printed in: *JZ* 66 (2011), 308–313, 308. Comprehensively on this subject, Augsberg (fn 21) 74f., 84.

⁶³ Thomas Vesting (2007) *Rechtstheorie: Ein Studienbuch*, München: Beck, 95 ff. speaks in this context of “social conventions and implicit knowledge”.

⁶⁴ Here recourse can be had to Wiethölter’s concept of proceduralisation as liberation of social normativity, Rudolf Wiethölter (2005) “Just-ifications of a Law of Society”, in: Oren Perez and Gunther Teubner (ed) *Paradoxes and Inconsistencies in the Law*, Oxford: Hart, 65-77, 71ff., 75.

⁶⁵ The USA has provided a model in the form of the “FDA Amendments Act” of 2007, Food and Drug Administration: FDA Amendments Act (FDAAA) of 2007, public law no. 110–85 § 801 (<http://www.gpo.gov/fdsys/pkg/PLAW-110publ85/pdf/PLAW-110publ85.pdf>). For the situation in Europe, Christian Quack and Alix Wackerbeck (2010) “Die Verpflichtung zur Registrierung und Veröffentlichung klinischer Studien: Darstellung der europäischen Rechtslage im Vergleich zur US-Regelung nach dem FDA Amendment Act”, 1 *GesundheitsRecht*, 6-12.

⁶⁶ Initial attempts are offered by the US governmental study register ClinicalTrials.gov or the German Register of Clinical Studies at the University Hospital of (www.germanctr.de). The impact of this issue is such that at European level also, over and above the EudraCT database (which is limited to access by the authorities of the Member States), public databases such as Eudra Pharm and the Clinical Trial

protection of constitutional rights only becomes effective through the cooperation of the specialist journals, which make registration of all studies carried out a precondition for publication.⁶⁷ Results for drugs, which are intended for distribution on the market, may only be published if the clinical studies on which they are based have been entered in the Clinical Trial Register and if all results have been included, both positive and negative.⁶⁸

Trial registration is particularly appropriate for dealing with the conflict between economic and scientific rationality. The duty of registration applies precisely from the point at which (as has been described above) manipulation is in a position to falsify the evolution of scientific knowledge. Unlike other possible sanctions, the duty of registration is aimed exactly at the critical selection mechanism upon which the interests of industry, science and healthcare come into conflict. Trial registration does not counteract repressive or prohibitive power techniques applied by the big pharmaceutical companies, operating instead as a corrective against their “seductive” manipulation techniques.⁶⁹ It ensures transparency, but – even more decisively – it stabilises and protects the very act of publication. Publication is no longer restricted to results, but is expanded to include the entire research project. And it does this before any results are known. It thus forces the parties to define their publication conduct under a veil of ignorance. At the very time when there is still uncertainty as to the results, research projects have to be made accessible to the medical public. The contingent nature of the research project is thereby made public. And publication practice faces a systematic pressure in regard to the frequency distribution of positive and negative results.

The duty of registration therefore comes into play precisely in regard to the selection mechanism of scientific evolution, a mechanism which (unlike individual court actions) does not operate solely in the individual case, but exerts a continuing influence on the joint development of industry, scientific knowledge, and medical practice. The duty of registration strengthens the scientific selection criterion of novelty, without consideration of positive or negative results, and weakens the economic selection criteria, which give rise to publication bias. And at the same time it strengthens the selection criteria for medical practice, for which knowledge concerning harmful side effects or indeed the lack of efficacy of a drug is just as important as information about positive curative effects. This tends to restore the intimate connection between research and publication, which bases the self-production of scientific knowledge, and which the seductive manipulation techniques of the pharmaceutical companies seek to sabotage.

Register are becoming established (www.eudrapharm.eu/eudrapharm/clinicaltrials.do and www.clinicaltrialsregister.eu).

⁶⁷ Catherine De Angelis and Jeffrey M. Drazen (2004) "Clinical Trial Registration: a Statement from the International Committee of Medical Journal Editors", 351 *The New England Journal of Medicine*, 1250-1251. There are also a few online journals that primarily publish negative results, for example the Journal of Negative Results in Biomedicine (<http://www.jnrnm.com/>). See Christian Pfeffer and Bjorn R. Olsen (2002) "Editorial: Journal of Negative Results in Biomedicine", 1 *Journal of Negative Results in BioMedicine*, 2.

⁶⁸ Journals can similarly counter the practice of ghostwriting, by making publication conditional upon the provision of details of the persons taking part in the study and its financing.

⁶⁹ Han makes reference to this decisive difference (fn 35). Constitutional rights against the “anonymous matrix” must therefore be structured differently from constitutional rights against state power, see Teubner (fn 24) 40ff.

4. Beyond the state's duties of protection: alternatives to state regulation of publication practice

In the generally accepted concept of the duty of protection we find the fourth weakness of the third party effect doctrine. Its state-centeredness is bound to be misleading: although it is private actors that are violating constitutional rights, the concept burdens the state with an obligation, and not the private actors themselves. This is particularly problematic in science, since the autonomy of the scientific community to some extent resists governmental duties to protect. By contrast, trial registration involves the social processes themselves, in order to protect science from being abused by industry. It takes up the particular dynamic of the conflict and protects the integrity of science from the inside, by motivating large numbers of private actors to become involved on the basis of their respective functional rationalities. In so doing it mobilises social forces to combat the expansionary tendencies of the pharmaceutical networks. As far as science is concerned, it functions almost like an immune system, which identifies and combats elements that are foreign to science.⁷⁰ There is certainly a political element here, but it does not operate as external state control, on the contrary it alters the internal self-reproduction of academic activity. State concepts of the duty to protect, which in the name of academic freedom impose duties of publication developed by legislative bodies, reduce the potential of autonomous scientific processes.⁷¹ Legislative standard setting underestimates the scientific community's need for autonomy and fails to take account of its evolutionary mechanisms. Moreover, it regards the actors involved as mere objects to be regulated. These actors however, are responsible (co-)authors in the protection of the autonomy of "their" respective social areas.⁷² As an alternative to regulatory responsibility of the state, therefore, a procedurally based reconnection of constitutional rights to society is proposed. Setting standards relating to constitutional rights is not an exclusive task of state policy, but primarily a function of societal self-organisation. The reason is "that no superior information exists outside of an emergent systematisation context regarding the possibilities of and the requirement for systematisation in this connection."⁷³ The state ought not then formulate comprehensive duties of protection; instead, its role should be limited to generally indirect forms of control through organisation and process.⁷⁴

⁷⁰ "Social systems need contradiction for their immune system, for the continuation of their self-reproduction under difficult circumstances." Niklas Luhmann (1995) *Social Systems*, Stanford: Stanford University Press, 385; idem (fn 42) 623.

⁷¹ Herein lies a problem with the new EU regulation on clinical studies (available from: <http://register.consilium.europa.eu/doc/srv?l=EN&t=PDF&gc=true&sc=false&f=ST%2017866%202013%20INIT>). Its implementation was decided by the European Council of Ministers on 20 December 2013. Insofar as the new regulation formulates a duty of registration in regard to clinical studies, it is reacting to social pressure, emanating from medical associations, ethics commissions, numerous NGOs and the Member States, to maintain the level of protection provided by social trial registration. An initial draft regulation of the EU Commission of July 2011 was exclusively aimed at the liberalisation and stabilisation of the pharmaceutical market in Europe. However, if the regulation goes beyond the duty of registration and standardises specific publication duties in regard to the nature and method of clinical study reports, it will infiltrate the differentiated publication forms of the scientific world, with unforeseeable consequences as far as the science community is concerned.

⁷² Oliver Gerstenberg (2001) "Private Law, Constitutionalism and the Limits of Judicial Role", in: Craig Scott (ed) *Torture as Tort: Comparative Perspectives on the Development of Transnational Human Rights Litigation*, Oxford: Hart Publishing, 687-703; Vagios Karavas (2006) *Digitale Grundrechte: Zur Drittwirkung der Grundrechte im Internet*, Baden-Baden: Nomos, 87ff., 99.

⁷³ Stichweh (fn 35) 84.

⁷⁴ Augsberg (fn 21) 80.

Trial registration thus takes accounts of the needs of science, because it protects academic freedom through a process of scientific self-regulation. It represents an alternative to the approach of a “plurality of financial sources”, an alternative that takes into account the particular nature of the conflict situation.⁷⁵ Trial registration has one outstanding feature: because it is the publishing houses that organise trial registration, they encourage the tendency to develop a specific (self-)control network that can stand up to the pharmaceutical networks.⁷⁶ In so doing it addresses the difficult and frequently discussed problem of how networks can be regulated when their decentralised structure means that they do not have any addressee.

This network consists of various social actors who, each having their own motives for doing so, are able to effect the protection contained within the register mechanism. The central role will be played by the specialist journals, if they make registration a precondition for publication. In addition they can accord a special weight to studies with negative results, either by publishing negative studies separately or by establishing a duty to take them into consideration in the peer review. The specialist journals are self-motivated, since they aim to maintain their function as a neutral medium of scientific knowledge in contradistinction to the mass media, and to avoid being used as a mere tool for advertising.⁷⁷

Universities, research funding institutions, scientific councils and medical associations can contribute to the success of trial registration.⁷⁸ By creating their own registers, internal registration obligations, ethics commissions and ombudsman proceedings, they reinforce the duty of registration, which has been created by the publishing houses.⁷⁹ Within science, the duty of registration raises the standard of care, because it requires the details of studies to be disclosed. Within health care, doctors will have a personal responsibility to inform themselves using study results published in the registers, and to correlate this information with the specialist journals. In addition, transnational control mechanisms will be able to prevent any attempts at circumventing trial registration, if transnational actors such as NGOs, the media and public interest litigation with their “scandalisation” strategies become involved with trial registration.⁸⁰ In 2007 WHO set up the registration network International Clinical Trials Registry Platform (ICTRP), in order to coordinate private

⁷⁵ On the plurality of financial sources as an institutional support of academic freedom, Christoph Graber (1994) *Zwischen Geist und Geld: Interferenzen von Kunst und Wirtschaft aus rechtlicher Sicht*, Baden-Baden: Nomos, 227 ff.

⁷⁶ A similar transformation of the academic world from the inside is described by Elke Wagner (2011) *Der Arzt und seine Kritiker: zum Strukturwandel medizinischer Öffentlichkeiten am Beispiel klinischer Ethik-Kommissionen*, Stuttgart: Lucius & Lucius.

⁷⁷ Cf. Ulrich Dirnagl and Martin Lauritzen (2010) "Fighting Publication Bias: Introducing the Negative Results Sections", 30 *Journal of Cerebral Blood Flow and Metabolism*, 1263-1264. Zu Initiativen innerhalb der wissenschaftlichen Publikationspraxis Martina Franzen (2011) *Breaking News: Wissenschaftliche Zeitschriften im Kampf um Aufmerksamkeit*, Baden-Baden: Nomos, 246ff.

⁷⁸ Thus the World Medical Association Declaration of Helsinki, following the extensions of 2000 and 2008, establishes the duty “to register each clinical study (...) in a publicly accessible database before recruitment of the first subject “ (Art. 35) and to publish negative studies (Art. 36), Available from: <http://www.wma.net/en/30publications/10policies/b3/index.html>.

⁷⁹ Such as the Ethical Commission of the Freiburg Medical Faculty (<http://www.uniklinik-freiburg.de/ethikkommission/live/antragstellung/gemaessMPG.html#Publikationsvorhaben>). Generally on this point, Andrew Jull, et al. (2002) "Clinical Trials in NZ: Does Anybody Know what's Going on?", 115 *The New Zealand Medical Journal*, 269.

⁸⁰ Concerning the role of the media and scandals in the uncovering of publication bias, see the above example cases.

and public activities relating to the registration of clinical studies on a worldwide scale.⁸¹ Private and public registers, which have to fulfil certain quality standards, feed their data into the metaregister on a regular basis. The aim is to ensure the quality of the register entries. The metaregister serves as a seal of quality in particular for smaller, private registers, and removes the burden of a standard international public register.

III. Conclusion: constitutional rights as conflict of laws rules

From this perspective, a clear distinction needs to be made between constitutional rights in state-citizen conflicts and constitutional rights in infra-societal conflicts. Traditional state-directed constitutional rights safeguard the relationship between the citizen and the state, but cannot lay any claim to forming a comprehensive value system for society or even a “common frame of reference”. At the bottom of infra-societal conflicts is such a great variety of communicative media that a unifying formula for both types of constitutional is excluded from the outset.⁸² Specific clashes between constitutional rights give rise to idiosyncratic conflict rules, which do not include any priority rules or burdens of justification, but which are characterised by the specific need for autonomy of the social areas affected.

Like the “hard won” defensive role of state-directed constitutional rights in the relationship between the citizen and the state, the self-constitution of academic freedom against intrusions of the economy, is a long-term process of boundary drawing. Just as state-directed constitutional rights have historically been won from state-citizen conflicts, academic freedom constitutes itself in the conflict with other social rationalities, in particular the rationality of economic action. The clash becomes a productive process, since it challenges science to define itself in the conflict.⁸³ This is the deeper reason why it is not sufficient to see the horizontal effect of constitutional rights as a transfer of positivised (state-directed) constitutional rights. Certainly the historical experience of state-directed constitutional rights is an element to be taken into consideration, and the protection level of the horizontal effect must be measured against this. Governmental obligations of protection are therefore not superfluous, but occupy a legitimate position alongside the potential solutions of the global regime conflicts involving industry, scientific research, and the healthcare system.⁸⁴

Within these conflicts, science has an opportunity to reformulate the limits of its autonomy under the pressure exerted by society’s conflicting rationalities. As far as the emergence of transnational constitutional rights is concerned, what Niklas Luhmann confirmed for the paradox of human rights also applies here:⁸⁵ It is in the direct experience of their violation, in cases of acute disappointment, that

⁸¹ World Health Organization (2012) International Clinical Trials Registry Platform (ICTRP), Available from: <http://www.who.int/ictrp/en>. Accessed 09/07/2012.

⁸² This is an extension of Luhmann’s argument, Luhmann (fn 26) 36.

⁸³ An analysis concerning the autonomy of science, Augsberg (fn 21) 74ff.

⁸⁴ For the concept of transnational regime, Andreas Fischer-Lescano and Gunther Teubner (2004) “Regime-Collisions: The Vain Search for Legal Unity in the Fragmentation of Global Law”, 25 *Michigan Law Journal of International Law*, 999-1045.

⁸⁵ Niklas Luhmann (1995) “Das Paradox der Menschenrechte und drei Formen seiner Entfaltung”, in: Niklas Luhmann (ed) *Soziologische Aufklärung 6: Die Soziologie und der Mensch*, Opladen: Westdeutscher Verlag, 229-236, 222.

constitutional rights acquire their shape and form. It is only when the selection mechanism of publication is violated that its significance for the way science operates is defined. This is how social conflicts work like natural experiments in the creation of law.

Constitutional rights as collective institutions – the formula emphasises their dual character as social process and legal process at one and the same time. Legal positivism must not be allowed to put the social dynamic of constitutional rights at risk. This dual character of constitutional rights allows them, in their collective-institutional dimension, to function as conflict of laws rules and as facilitator of social differentiation. This is the reason why they elude any unified legal formula for state-citizen conflicts and for infra-societal conflicts. Instead of defining common constitutional rights standards that apply to both state and society,⁸⁶ the law needs constantly to react to the formation of normativity in diverse social discourses in a context-sensitive manner.⁸⁷ The law can act as an anchor for the creative development of the dynamics of social areas, but must not prescribe their content.⁸⁸ Understood in this way, legal obligations of protection vis-à-vis the self-regulation of society are directed not towards content but towards procedures. The task of the law would be to set up areas of protection in which social counter-institutions - in our case, trial registration - are able to develop.⁸⁹ By mobilising and multiplying dissenting voices, trial registration ensures that research results that run against economic interests cannot be manipulated. It provides a more appropriate counter-institution to the publication bias than any state regulation could achieve. Because trial registration shifts the focus on to an enabling law, it has the potential to strengthen the scientific world against the economy's expansionary tendencies.

Ahmed, Ikhlmaq, Alexander Sutton and Richard Riley (2012) "Assessment of Publication Bias, Selection Bias, and Unavailable Data in Meta-analyses Using Individual Participant Data: a Database Survey", 344 *BMJ*, d7762.

Alexy, Robert (2002) "Verfassungsrecht und einfaches Recht - Verfassungsgerichtsbarkeit und Fachgerichtsbarkeit", 61 *VVdStRL*, 7ff.

Applegate, William B., Curt D. Furberg and Robert P. Byington (1996) "The Multicenter Isradipine Diuretic Atherosclerosis Study (Midas)", 277 *Journal of the American Medical Association*, 297-298.

Augsberg, Ino (2012) "Subjektive und objektive Dimensionen der Wissenschaftsfreiheit.", in: Friedemann Voigt (ed.): *Freiheit der Wissenschaft. Beiträge zu ihrer Bedeutung, Normativität und Funktion*. Berlin: De Gruyter, 65-89.

⁸⁶ However, (for example) the understanding of European constitutional rights as an expression of a common belief in constitutional rights accords with this. See Jürgen Philipp Terhechte (2011) *Konstitutionalisierung und Normativität der europäischen Grundrechte*, Tübingen: Mohr Siebeck, 3ff.

⁸⁷ Selznick (fn 59) 32ff.; Luhmann (fn 26) 192.

⁸⁸ On the structural primacy of learning in world society and a shift in the law towards facilitating cognitive expectations, Niklas Luhmann (1990) "The World Society as a Social System", in: Niklas Luhmann (ed) *Essays on Self-Reference*, New York: Columbia University Press, 175-190.

⁸⁹ Concerning such an impartially "partisan" law, which is in favour of social autonomy but which exercises this "partisanship" on an impartial basis, Wiethölter (fn 64). On law as an anchor, Christensen and Fischer-Lescano (fn 15) 316.

Becker, Annette and Fatma Dörter (2011) "The Association between a Journal's Source of Revenue and the Drug Recommendations Made in the Articles it Publishes", 183 Canadian Medical Association Journal, 544-548.

Bombardier, Claire, Loren Laine and Alise Reicin (2000) "Comparison of Upper Gastrointestinal Toxicity of Rofecoxib and Naproxen in Patients with Rheumatoid Arthritis.VIGOR Study Group", 343 The New England Journal of Medicine, 1520-1528.

Bumke, Christian (2009) "Universitäten im Wettbewerb", 69 Veröffentlichungen der Vereinigung der Deutschen Staatsrechtslehrer, 407-461.

Chan, An-Wen, Asbjorn Hróbjartsson and Mette T. Haahr (2004) "Empirical Evidence for Selective Reporting of Outcomes in Randomized Trials: Comparison of Protocols to Published Articles", 291 Journal of the American Medical Association, 2457-2465.

Christensen, Ralph and Andreas Fischer-Lescano (2007) Das Ganze des Rechts. Vom hierarchischen zum reflexiven Verständnis deutscher und europäischer Grundrechte, Berlin: Duncker & Humblot.

Cicero, Marcus Tullius (1896) De natura deorum, London: Methuen.

Clapham, Andrew (2006) Human Rights Obligations of Non-State Actors, Oxford: Oxford University Press.

Conrad, Dieter (1965) Freiheitsrechte und Arbeitsverfassung, 1965, Berlin: Duncker & Humblot.

De Angelis, Catherine and Jeffrey M. Drazen (2004) "Clinical Trial Registration: a Statement from the International Committee of Medical Journal Editors", 351 The New England Journal of Medicine, 1250-1251.

Dickersin, Kay (1990) "The Existence of Publication Bias and Risk Factors for its Occurrence", 263 Journal of the American Medical Association, 1385-1389.

Dickersin, Kay, Yuan-I Min and Curtis L. Meinert (1992) "Factors Influencing Publication of Research Results. Followup of Applications Submitted to two Institutional Review Boards", 267 Journal of the American Medical Association, 374-378.

Dirnagl, Ulrich and Martin Lauritzen (2010) "Fighting Publication Bias: Introducing the Negative Results Sections", 30 Journal of Cerebral Blood Flow and Metabolism, 1263-1264.

Dreier, Horst (1993) Dimensionen der Grundrechte. Von der Wertordnungsjudikatur zu den objektiv-rechtlichen Grundrechtsgehalten, Hannover: Hennies & Zinkeisen.

Dürig, Günter (1956) "Grundrechte und Zivilrechtsprechung", in: Theodor Maunz (ed.): Vom Bonner Grundgesetz zur gesamtdeutschen Verfassung: Festschrift Hans Nawiasky. München: Isar, 157-210.

- (1957) in: Günter Dürig and Theodor Maunz (ed.): Grundgesetz. Kommentar. München: C.H. Beck, Art.1 Rn. 5ff.

Easterbrook, Philippa J., Jesse A. Berlin, Ramana Gopalan and DR. Matthews (1991) "Publication Bias in Clinical Research", 337 The Lancet, 867-872.

Editors, The PLoS Medicine, Virginia Barbour, Jocalyn Clark and Susan Jones (2011) "Ghostwriting Revisited: New Perspectives but Few Solutions in Sight", 8 PLoS Medicine, e1001084.

Eyding, Dirk, Monika Lelgemann and Ulrich Grouven (2010) "Reboxetine for a Cute Treatment of Major Depression: Sytematic Review and Meta-Analysis of Published and Unpublished Placebo and Selective Serotonin Reuptake Inhibitor Controlled Trials", BMJ, c4737.

Fanelli, Daniele (2010) "Do Pressures to Publish Increase Scientists' Bias? An Empirical Support from US States Data", 5 PLoS ONE, 1-7.

Fischer-Lescano, Andreas (2008) "Kritik der praktischen Konkordanz", 2 Kritische Justiz, 166-177.

Fischer-Lescano, Andreas and Gunther Teubner (2004) "Regime-Collisions: The Vain Search for Legal Unity in the Fragmentation of Global Law", 25 Michigan Law Journal of International Law, 999-1045.

Franzen, Martina (2011) Breaking News: Wissenschaftliche Zeitschriften im Kampf um Aufmerksamkeit, Baden-Baden: Nomos.

Fugh-Berman, Adriane J. (2010) "The Haunting of Medical Journals: How Ghostwriting Sold "HRT"", 7 PLoS Medicine, e1000335.

Galtung, Johan (1965) "Institutionalized Conflict Resolution: A Theoretical Paradigm", 2 Journal of Peace Research, 348-397.

Gamillscheg, Franz (1964) "Die Grundrechte im Arbeitsrecht", 164 Archiv für die civilistische Praxis, 385-445.

Gardbaum, Stephen (2003) "The 'Horizontal Effect' of Constitutional Rights", 102 Michigan Law Review, 387-459.

Gelling, Lesli (2013) "Negative Results have a value", 20 Nurse Researcher, 3.

Gerstenberg, Oliver (2001) "Private Law, Constitutionalism and the Limits of Judicial Role", in: Craig Scott (ed.): Torture as Tort: Comparative Perspectives on the Development of Transnational Human Rights Litigation. Oxford: Hart Publishing, 687-703.

Gesundheitswesen, Institut für Qualität und Wirtschaftlichkeit im (2011) "Bupropion, Mirtazapin und Reboxetin zur Behandlung der Depression - A05-20C-Abschlussbericht",

Graber, Christoph (1994) Zwischen Geist und Geld: Interferenzen von Kunst und Wirtschaft aus rechtlicher Sicher, Baden-Baden: Nomos.

Han, Byung-Chul (2014) "Im digitalen Panoptikum: Wir fühlen uns frei. Aber wir sind es nicht. ", 2 Der Spiegel,

Hesse, Konrad (1999) Grundzüge des Verfassungsrechts der Bundesrepublik Deutschland, 4. Heidelberg: C.F. Müller.

Horton, Richard (1997) "Medical Editors Trial Amnesty", 350 The Lancet, 756.

Jäger, Herbert (1989) Makrokriminalität: Studien zur Kriminologie kollektiver Gewalt, Frankfurt: Suhrkamp.

Jefferson, Tom, Mark Jones, P. Doshi, CB. Del Mar, CJ. Heneghan, R. Hama and MJ. Thompson (2012) "Neuraminidase Inhibitors for Preventing and Treating Influenza in Healthy Adults and Children", Cochrane Database of Systematic Reviews, Art. No.: CD008965.

Jull, Andrew, Iain Chalmers and Anthony Rodgers (2002) "Clinical Trials in NZ: Does Anybody Know what's Going on?", 115 The New Zealand Medical Journal, 269.

Karavas, Vagios (2006) Digitale Grundrechte: Zur Drittwirkung der Grundrechte im Internet, Baden-Baden: Nomos.

Kesselheim, Aaron (2011) "Covert Pharmaceutical Promotion in Free Medical Journals", 183 Canadian Medical Association Journal, 534-535.

Krimsky, Sheldon (2003) Science in the Public Interest: Has the Lure of Profits Corrupted Biomedical Research?, New York: Rowman & Littlefield Publishers.

Ladeur, Karl-Heinz (2004) Kritik der Abwägung in der Grundrechtsdogmatik, Tübingen: Mohr Siebeck.

- (2007) Das Medienrecht und die Ökonomie der Aufmerksamkeit. In Sachen Dieter Bohlen, Maxim Biller, Caroline von Monaco u.a., Köln: Halem.

Lenski, Sophie-Charlotte (2007) *Personenbezogene Massenkommunikation als verfassungsrechtliches Problem: Das allgemeine Persönlichkeitsrecht in Konflikt mit Medien, Kunst und Wissenschaft*, Berlin: Duncker & Humblot.

Lexchin, Joel, Lisa Bero, Benjamin Djulbegovic and Otavio Clark (2003) "Pharmaceutical Industry Sponsorship and Research Outcome and Quality: Systematic Review", 326 *BMJ*, 1167-1177.

Luhmann, Niklas (1965) *Grundrechte als Institution: Ein Beitrag zur politischen Soziologie*, Berlin: Duncker & Humblot.

- (1990) *Die Wissenschaft der Gesellschaft*, Frankfurt: Suhrkamp.
- (1990) "The World Society as a Social System", in: Niklas Luhmann (ed.): *Essays on Self-Reference*. New York: Columbia University Press, 175-190.
- (1995) "Das Paradox der Menschenrechte und drei Formen seiner Entfaltung", in: Niklas Luhmann (ed.): *Soziologische Aufklärung 6: Die Soziologie und der Mensch*. Opladen: Westdeutscher Verlag, 229-236.
- (1995) *Social Systems*, Stanford: Stanford University Press.
- (2013) *Theory of Society*, Stanford: Stanford University Press.

Mathews, Jud and Alec Stone Sweet (2011) "All Things in Proportion? American Rights Review and the Problem of Balancing", 4 *Emory Law Journal*, 102-179, 116.

Medwedjew, Shores A. (1971) *Der Fall Lyssenko. Eine Wissenschaft kapituliert*, Hamburg: Hoffmann & Campe.

Nowotny, Helga (2005) "The Changing Nature of Public Science", in: Helga Nowotny (ed.): *The Public Nature of Science under Assault. Politics, Markets, Science and the Law*. Berlin-Heidelberg: Springer, 1-28.

Nowrot, Karsten (2007) "Den „Kinderschuh“ entwachsen: Die (Wieder-) Entdeckung der rechtssoziologischen Perspektive in der Dogmatik der Völkerrechtssubjektivität", 28 *Zeitschrift für Rechtssoziologie*, 21-48.

Petryna, Adriana (2009) *When Experiments Travel: Clinical Trials and the Global Search for Human Subjects*, Princeton: Princeton University Press.

Pfeffer, Christian and Bjorn R. Olsen (2002) "Editorial: Journal of Negative Results in Biomedicine", 1 *Journal of Negative Results in BioMedicine*, 2.

Quack, Christian and Alix Wackerbeck (2010) "Die Verpflichtung zur Registrierung und Veröffentlichung klinischer Studien: Darstellung der europäischen Rechtslage im Vergleich zur US-Regelung nach dem FDA Amendment Act", 1 *GesundheitsRecht*, 6-12.

Ridder, Helmut (1963) *Die Freiheit der Kunst nach dem Grundgesetz*, Berlin: Vahlen.

- (1975) *Die soziale Ordnung des Grundgesetzes*, Opladen: Westdeutscher Verlag.

Rüfner, Wolfgang (2011) "Grundrechtsadressaten", in: Josef Isensee and Paul Kirchhof (ed.): *Handbuch des Staatsrechts der Bundesrepublik Deutschland*. Heidelberg: C.F. Müller, Rn. 83-125.

Ruggie, John (7 April 2008) "Protect, Respect, and Remedy: A Framework for Business and Human Rights, Report of the Special Representative of the Secretary-General on Human Rights and Transnational Corporations and Other Business Enterprises, A/HRC/8/5", 6-13.

Schaaber, Jörg, Michael Kochen, Bruno Müller-Oerlinghausen and Wilhelm Niebling (2011) "Warum unabhängige Arzneimittelzeitschriften und Fortbildungsveranstaltungen wichtig sind", in: Klaus Lieb, David Klemperer, Wolf-Dieter Ludwig and Michael Kochen (ed.): *Interessenskonflikte in der Medizin – Hintergründe und Lösungsmöglichkeiten*. Berlin, Heidelberg: Springer, 237ff., 244ff.

Schierbeck, Jens (2000) "Operational Measures for Identifying and Implementing Human Rights Issues in Corporate Operations", in: Asbjorn Eide, Ole Bergesen and Pia Goyer (ed.): Human Rights and the Oil Industry Antwerpen: Intersentia, 161-177.

Schmidt-Aßmann, Eberhard (2000) "Wissenschaftsplanung im Wandel", in: Wilfried Erbguth, Janbernd Oebbecke and Hans-Werner Rengeling (ed.): Planung. Festschrift für Werner Hoppe zum 70. Geburtstag. München: C.H. Beck, 649-665.

- (2005) "Wissenschaft – Öffentlichkeit – Recht", in: Horst Dreier (ed.): Rechts- und staatsrechtliche Schlüsselbegriffe: Legitimität – Repräsentation – Freiheit, Symposium für Hasso Hofmann zum 70. Geburtstag. Berlin: Duncker & Humblot, 67ff.

Schmitt, Carl (1985 (1931)) "Freiheitsrechte und institutionelle Garantien der Reichsverfassung", in: Carl Schmitt (ed.): Verfassungsrechtliche Aufsätze aus den Jahren 1924-1954. Berlin: 140-178.

Schott, Gisela, Henry Pacht and U. Limbach (2010) "Finanzierung von Arzneimittelstudien durch pharmazeutische Unternehmen und die Folgen; Teil1: qualitative systematische Literaturübersicht zum Einfluss auf Studienergebnisse, -protokoll und qualität", 107 Deutsches Ärzteblatt international, 279-285.

- (2010) "Finanzierung von Arzneimittelstudien durch pharmazeutische Unternehmen und die Folgen; Teil2: qualitative systematische Literaturübersicht zum Einfluss auf Autorenschaft, Zugang zu Studiendaten sowie -registrierung und Publikation", 107 Deutsches Ärzteblatt international, 295-301.

Schwabe, Jürgen (1971) Die sogenannte Drittwirkung der Grundrechte. Zur Einwirkung der Grundrechte auf den Privatrechtsverkehr, München: Goldmann.

Selznick, Philip (1969) Law, Society and Industrial Justice, New York: Russell Sage.

Smith, M.L. (1980) "Publicationbias and Meta-analysis", 4 Evaluation in Education, 22-24.

Steinhauer, Fabian (2013) "Das Grundrecht der Kunstfreiheit: Kommentar zu einem Grundlagentext von Helmut Ridder", Manuskript Frankfurt,

Stern, Jerome and R. John Simes (1997) "Publication Bias: Evidence of Delayed Publication in a Cohort Study of Clinical Research Projects", 315 BMJ, 640-645.

Stichweh, Rudolf (1994) Wissenschaft, Universität, Professionen, Frankfurt: Suhrkamp.

- (2007) "Einheit und Differenz im Wissenschaftssystem der Moderne", in: Jost Halfmann and Johannes Rohbeck (ed.): Zwei Kulturen der Wissenschaft - revisited. Weilerswist: Velbrück, 213-228.

Stolleis, Michael (2012) Geschichte des öffentlichen Rechts in Deutschland IV, München: C.H. Beck.

Sutton, Alexander, Sue J. Duval and RL. Tweedie (2000) "Empirical Assessment of Effect of Publication Bias on Meta-analysis", 320 BMJ, 1574-1577.

Terhechte, Jürgen Philipp (2011) Konstitutionalisierung und Normativität der europäischen Grundrechte, Tübingen: Mohr Siebeck.

Teubner, Gunther (2006) "The Anonymous Matrix: Human Rights Violations by 'Private' Transnational Actors", 69 Modern Law Review, 327-346.

- (2012) Constitutional Fragments: Societal Constitutionalism and Globalization, Oxford: Oxford University Press.

Tonks, Alison (2002) "A Clinical Trials Register for Europe", 325 BMJ, 1314-1315.

Tramèr, Martin R., D. John Reynolds, Andrew Moore and Henry McQuay (1997) "Impact of Covert Duplicate Publication on Meta-analysis: a Case Study", 315 BMJ, 635-640.

Verschraegen, Gert (2013) "Differentiation and Inclusion: A Neglected Sociological Approach to Fundamental Rights ", in: Mikael Rask Madsen and Gert Verschraegen

- (ed.): Making Human Rights Intelligible: Towards a Sociology of Human Rights. Oxford: Hart, 25-60.*
- Vesting, Thomas (2007) Rechtstheorie: Ein Studienbuch, München: Beck.*
- (2013) "Die Tagesschau-App und die Notwendigkeit der Schaffung eines „Intermedienkollisionsrechts“, in: Indra Spiecker (ed.): Karlsruher Dialog zum Informationsrecht. Karlsruhe: KIT Scientific Publishing, 1ff.*
- Viellechner, Lars (2013) Transnationalisierung des Rechts, Weilerswist: Velbrück.*
- Viens, A.M. and Julian Savulescu (2004) "Introduction to The Olivieri Symposium", 30 Journal of medical ethics, 1-7.*
- Wagner, Elke (2011) Der Arzt und seine Kritiker: zum Strukturwandel medizinkritischer Öffentlichkeiten am Beispiel klinischer Ethik-Kommissionen, Stuttgart: Lucius & Lucius.*
- Weber, Max (1968) Gesammelte Aufsätze zur Wissenschaftslehre, Tübingen: Mohr Siebeck.*
- Wiethölter, Rudolf (2005) "Just-ifications of a Law of Society", in: Oren Perez and Gunther Teubner (ed.): Paradoxes and Inconsistencies in the Law. Oxford: Hart, 65-77.*
- Zöllner, Wolfgang (1996) "Regelungsspielräume im Schuldvertragsrecht: Bemerkungen zur Grundrechtsanwendung im Privatrecht und zu den sogenannten Ungleichgewichtslagen", 196 Archiv für die civilistische Praxis, 1-36.*