# Transparency First: Disclosure of conflict of interest in the psychosocial field.*

Peter Lehmann

SUMMARY: Using the example of the position of the European Network of (Ex-)Users and Survivors of Psychiatry (ENUSP), the author demonstrates the importance of transparency and disclosure of conflicts of interest for psychiatric patients, their relatives and friends, health care practitioners and providers, patients' organisations and the public.

KEY WORDS: Conflict of interest, transparency, *Shedding Light*, Mental Health Europe

On January 23, 2019, a hearing was held in the European Parliament on the subject of 'Shedding Light on transparent collaboration in healthcare: a unique overview of practices in Europe', initiated by Mental Health Europe (MHE), a European federation of national non-governmental organisations in the psychosocial field. 'Shedding Light' is a project run by MHE and supported through a grant from the Mental Health Initiative, Open Society Foundations.

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Peter Lehmann is a psychiatric survivor, activist and publisher. See: www.peter-lehmann.de. Contact: mail@peter-lehmann.de.

## Shedding Light

The main objective of *Shedding Light* is to raise awareness about the importance of transparency in the field of psychiatry and to encourage the adoption of sunshine and transparency laws across Europe; in other word, to force psychiatric professionals and the pharmaceutical industry to disclose their hidden (and profit-orientated) connections:

MHE is concerned by the undue influence of the health industry, especially the pharmaceutical industry, on healthcare since it may bring substantial risks for public health, users of mental health services and patients. This influence can result in altered prescribing behaviour, over-medicalisation, biased research results and Clinical Practice Guidelines, off-label use of medicines and biased reimbursement decisions. (MHE, 2019)

Together with Dainius Pūras (UN Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of health), who spoke about 'Transparency and the right to mental health', and Klaus Lieb (Psychiatrist, Mainz University Medical Center), who spoke about 'Conflicts of interest in medical practice and how it may harm patients', Peter Lehmann speaking on behalf of ENUSP, explained the need for *Achievement of Full Human Rights and Appropriate Support for People With Mental Health Problems and Psychosocial Disabilities* and *The right approach to ensure greater transparency of cooperation between the health care industry, HCPs, and HCOs.* ENUSP is the only independent federation at European level composed exclusively of and directly representing (ex-) users and survivors of psychiatry, with 32 member organizations and 42 individual members in 26 countries.

For this hearing and based on the MHE desk research phase (Rodzinka et al., 2019), the Board of ENUSP delivered the condensed paper *Why transparency in healthcare matters to users and patients* (ENUSP, 2019) on the obligation of psychosocial stakeholders to declare potential conflicts of interest and the obligation to disclose transfers of values between the health care industry, health care practitioners (HCPs), and health care organisations (HCOs).

## Transparency in the Work of Organisations

As the ENUSP Board explained, ENUSP has never accepted any contribution of any kind from the pharmaceutical industry. Other organisations may deal with such support differently, but have been called on to support – like ENUSP – the position paper of the European Public Health Alliance (2001) on the independence of patients' organisations. According to this position, all organizations that accept funds from the pharmaceutical industry should, at a minimum, determine an upper limit to the proportion of industry sponsorship

and their total income; they should also articulate clearly the role of the sponsoring body in relation to sponsored projects and to the organisation as a whole in their statutes.

## Achievement of Full Human Rights and Appropriate Support for People with Psychiatric Problems

ENUSP has no other commitment than the basic interests of users and survivors of psychiatry: enforcing their full human rights, especially the right to life and bodily integrity; enforcing the right to adequate and effective assistance in case of mental distress of a social, psychosocial or even biological nature, the right to the best medical treatment in case of mental distress that is of a physiological nature, but always based on the Hippocratic Oath (Nil nocere – first, do no harm), safeguarding their civil rights in treatment and rehabilitation on a par with somatic patients and their equal participation in society.

At the 1999 *Balancing Mental Health Promotion and Mental Health Care: A Joint World Health Organization / European Commission Meeting* in Brussels, among others, these common goals and strategies to advance mental health promotion and care were defined:

- Developing innovative and comprehensive, explicit mental health policies in consultation with all stakeholders, including users and carers
- Development of new non-stigmatising and self-help approaches
- Development of mental health legislation based on human rights, emphasising freedom of choice (World Health Organization / European Commission).

But until now from mainstream HCPs and HCOs, there has not been much support to reach those goals and strategies to advance mental health promotion and care, and there has also not been support from the health care industry. In fact, they have prevented the development of non-medical approaches by propagating and supporting the myth of a chemical imbalance as the main cause for depression and psychosis (Whitaker, 2010). In 2017, Dainius Pūras, the United Nations Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health, explained to the UN General Assembly:

> However, the field of mental health continues to be over-medicalized and the reductionist biomedical model, with support from psychiatry and the pharmaceutical industry, dominates clinical practice, policy, research agendas, medical education and investment in mental health around the world. The majority of mental health investments in low-, middle- and high-income

> countries disproportionately fund services based on the biomedical model of psychiatry. There is also a bias towards first-line treatment with psychotropic medications, in spite of accumulating evidence that they are not as effective as previously thought, that they produce harmful side effects and, in the case of antidepressants, specifically for mild and moderate depression, the benefit experienced can be attributed to a placebo effect. Despite those risks, psychotropic medications are increasingly being used in high-, middle- and low-income countries across the world. We have been sold a myth that the best solutions for addressing mental health challenges are medications and other biomedical interventions. (*Report of the Special Rapporteur*)

The health care industry supported and/or supports not only psychiatric mainstream HCOs in different ways, but also parents' organisations such as European Federation of Associations of Families of People with Mental Illness (EUFAMI), 'patients' organisations like the Global Alliance of Mental Illness Advocacy Networks (GAMIAN-Europe), as well as publishers and journalists, who all receive major consideration, mostly for the promotion of new, patented and expensive drugs and mostly in a untransparent way. A lack of transparency is also very often present in the practice of lobbying parliamentarians internationally and nationally.

GAMIAN-Europe, for example, calls the drug industry funding it receives – their main source of income – in the so-called Transparency Register of the European Union 'other sources' (EU, 2009). The same goes with an increasing tendency for the financial report on their website. In June 2018, information which is no longer available on GAMIAN-Europe's web site disclosed that in 2016-2017, the organization received €152,762.07 from Janssen, Lundbeck, Otsuka, Pfizer, and Shire, an industry funding quote of 70% of their total income. Referring to their 2017-2018 financial report now on line, the total industry related income grew to €158,388.93 (72% of their total income). However, the identity of the drug firms is no longer mentioned here, with simply the information that the full financial report is available at the commercial court of Brussels (GAMIAN-Europe, undated). EUFAMI's situation is similar. They also report the origin of their income in the Transparency Register of the European Union intransparently and speak like GAMIAN-Europe, of 'other sources' (EU, 2016). You have to find these 'other sources' on their website – grants from their collaborating partners Janssen, Lundbeck, and Otsuka (EUFAMI, 2017, p. 22). Both examples document the inadequacy of existing transparency registers and 'self-regulation' systems.

HCPs are supported by transfers of values from the health care industry to influence the development of new diagnoses for the DSM and ICD or to influence guidelines in commissions, to give lectures, write articles or books or give their names as authors and researchers to promote their drugs. These promotions are

often part of extra-occupational education for medical doctors and more or less all such events suggest special expensive substances and high dosages. Other transfers of values also occur with the participation of HCPs in observational phase IV-studies where money is paid for suggesting patients to be included. Even direct participation in drug sales can happen. In general, all these transfers of values happen in a hidden way. The amount of money and the contracts covering those transfers and their purposes are hidden. The health care industry delivers values for psychoeducation; professionals in the psychosocial field use these materials, particularly for administration of neuroleptics, for example. The story told is, the adverse effects of so-called atypical neuroleptics are mild compared with traditional neuroleptics (Lehmann, 2013). Psychiatrists such as Gerhard Ebner (former President of the Swiss Association of Psychiatric Medical Directors, who served also on Janssen Pharmaceuticals' Advisory Board regarding the introduction of Risperdal Consta, the first 'atypical' depot neuroleptic) have clearly stated that newer neuroleptics do not have fewer adverse effects. Regarding the new 'atypical' neuroleptics, he said in 2003:

> It is not a case of fewer side-effects, but of different ones which can be just as debilitating even if the patient isn't immediately aware of them. Therefore, patients can be more easily motivated to take these drugs because they no longer suffer instantly and as much from the excruciating dyskinesias/ extrapyramidal side-effects. (p. 30)

There is a lot of literature about these influencers in the health care industry. The efficacy of psychiatric drugs is systematically overestimated, and harm is systematically underestimated (Hengartner, 2017). Some authors even speak of manipulation and corruption (see, for example: Angell, 2004; Perlis et al., 2005; Law, 2007; Weiss, 2008; Olsen, 2009; Fromm & Rickelmann, 2010; Cosgrove & Krimsky, 2012; Virapen, 2012; Gøtzsche, 2013; Gøtzsche, 2015; Ansari & Ansari, 2016; Sheller et al., 2018). Some authors conclude that transparency alone would not solve the problem of manipulation; they suggest that members in committees, panels and other commissions which decide about guidelines, revisions of diagnoses, etc. should be free of all conflicts of interest (Cosgrove et al., 2014). Giovanni Fava from the Department of Psychology at the University of Bologna stated:

> The issue of conflicts of interest has brought clinical medicine to an unprecedented crisis of credibility. The situation of psychiatry does not appear to be different from other areas of medicine. (2007, p. 19)

It is self-evident, that no medical treatment is free of risks. But the consideration of the pros and cons, according to the law and the UN Convention on the Rights

of Persons with Disabilities, is the right and responsibility of the patient, after receiving effective information on risks, potential damages and alternatives. This is why full transparency is needed. As an example of how information can look if developed free from the influence of drug companies, it is worth mentioning the recent innovative and successful project in the German Federal State Rhineland-Palatinate (RLP). Patient information leaflets used in Germany (where no regulations exist on the disclosure of conflicts of interest) have always been published or sponsored by the pharmaceutical industry and completely biased. These new information brochures now include risks and damages, and alternatives currently available even in ordinary psychiatric wards. Withdrawal problems and critical information sources are mentioned as well, and the State of RLP provided financial support to this project (NetzG-RLP, 2018a, 2018b). The health care industry and collaborating HCPs, however, had failed to deliver balanced information sheets on their products.

The interests of drug companies are first of all the interests of their shareholders; if the management of drug firms was first of all working in the interests of patients, they would probably lose their jobs sooner or later. Supporting alternatives beyond psychiatry that de-emphasise psychopharmacology could lower sales rates and share values. Up until now, no company has been prepared to take such a risk.

## Need for Unrestricted Transparency

Within ENUSP, assessing the administration and taking of products of the pharmacological industry is a controversial issue; people are different. Some are adamantly against taking psychiatric drugs based on the knowledge of their effects or previous experience and others find drugs helpful at certain points. Either way, some individuals demand easy access to financial compensation when their health is damaged by products of the pharmacological industry, a right to support even when they refuse to take psychotropic drugs, and appropriate alternative non-psychiatric support (Lehmann, 1997).

But over all, for ENUSP the reduced life expectancy of persons who have received serious psychiatric diagnoses (such as 'schizophrenia', 'bipolar disorder', 'major depression', and 'personality disorder') is a vital issue to address. In particular, people diagnosed with schizophrenia (and treated for such) have a risk of dying on average twenty-two years earlier than others in Europe.

There is a major public health risk with large-scale dissemination of psychiatric drugs whose so-called side-effects often are hidden or downplayed. Adverse effects of drugs is the main cause of death following inappropriate prescriptions according to the European Commission, but, more importantly, also following prescriptions based on diagnostic manuals and according to publications in the medical literature.

Adverse effects can occur independently of diagnosis or drug dosage. Neuroleptics, for example, can produce changes in the brain structure and liver mitochondria even in 'therapeutic doses', in low doses and after short-term administration. The same applies to dystonic disorders, Parkinsonian disorders, tardive dyskinesia, hyperthermia, disorders of the pancreas hormone system, elevated prolactin levels which are associated with sexual disorders and neoplasm in the mammary glands, agranulocytosis, tachycardia, circulatory insufficiency, systemic allergic reactions, and depression with suicidality (see Lehmann, 2019a).

To complicate the matter, it is still not possible to predict how a psychiatric drug might work in an individual patient. In 1964, Heinrich Kranz, a former President of the German Society for Psychiatry and Neurology, confessed that his profession has

> ... learned that, at therapeutically flawless and even low doses, harmful concomitant effects and potentially lethal outcomes can occur – due to still largely unknown individual dispositions or other complicating factors that we hardly survey. (p. 201)

But in its 2012 newsletter *Choices in Recovery*, Janssen Pharmaceuticals, Inc. commented on the increased mortality rate in psychiatric patients, acknowledging that

> [r]esearch has shown that the life expectancy for people living with a serious mental health condition is, on average, 25 years shorter than the general population. Heart disease, diabetes, respiratory diseases, and infectious diseases (such as HIV/AIDS) are the most common causes of death among this population.

However and perhaps understandably, the company failed to accept a connection with the drugs it produces and sells, although heart disease, diabetes, respiratory diseases and infections due to a weakened immune system are well-known adverse effects of their drugs and may occur very often.

Numerous other research has shown a clear link between psychiatric drugs (especially neuroleptics) and reduced life expectancy (see, for example, Newman et al., 1991; Ösby et al., 2000; Colton & Manderscheid, 2006; Manderscheid, 2006, 2009; Weinmann et al., 2009; Aderhold, 2010; Chang et al., 2011; Laursen et al., 2012; Tenback et al., 2012; Ringen et al., 2014; Walker et al., 2015). Some researchers with links to the pharmaceutical industry like Jari Tiihonen from the Department of Forensic Psychiatry at the University of Eastern Finland in Kuopio and colleagues however have tended to deny such links. They stated that

> [i]n patients with one or more filled prescription for an antipsychotic drug, an inverse relation between mortality and duration of cumulative use was noted. (2009, p. 620)

In a declaration on conflicts of interest two years later, Tiihonen had to disclose:

> Dr. Tiihonen has served as a consultant to Lundbeck, Organon, Janssen-Cilag, Eli Lilly, AstraZeneca, Hoffmann-La Roche, and Bristol-Myers Squibb and has received fees for giving expert opinions to Bristol-Myers Squibb and GlaxoSmithKline and lecture fees from Janssen-Cilag, Bristol-MyersSquibb, Eli Lilly, Pfizer, Lundbeck, GlaxoSmithKline, and AstraZeneca. (Tiihonen et al., 2011, p. 608)

Comparable statements were made by Hans-Jürgen Möller, Chair of the Psychiatric University Clinic in Munich and then also Chair of the World Psychiatric Association's Section on Pharmacopsychiatry, and by Harold Sackeim from the Department of Psychiatry at Columbia University's College of Physicians and Surgeons in New York City. Although the question of whether there is dependence on neuroleptics is highly controversial, and some high-ranking psychiatrists, such as the former President of the German Psychiatric Association, Rudolf Degkwitz, have spoken since the 1960s of a significant risk of dependence (cf. Lehmann, 2018; Kaufmann & Lehmann, 2019), Möller claimed:

> Compared to benzodiazepines, neuroleptics have the great advantage that they do not lead to dependence. The very problem that makes the use of benzodiazepines so questionable does not arise at all. (p. 386)

Nearly a quarter of a century later, in a declaration of conflicts of interest, he disclosed that he received research funding or is or has been a member of the Advisory Board or has received fees for presentations by AstraZeneca, Bristol-Myers Squibb, Eisai, Eli Lilly, GlaxoSmithKline, Janssen Cilag, Lundbeck, Merck, Novartis, Organon, Pfizer, Sanofi-Aventis, Sepracor, Servier and Wyeth. (Möller, 2009). Sackeim is in a similar situation. Referring to the administration of electroshock and its 'benefits', Sackeim claimed its general life-prolonging effect – contrary to psychiatric publications on dangerous electroshock effects, such as cerebral haemorrhage, status epilepticus, accumulation of fluid in the lungs and respiratory arrest, a five-fold increase in suicide rate in the week following electroshock, life-threatening heart rhythm and blood pressure disorders, pneumonia due to aspiration of external substances into the lungs, complications of lung function (e.g. asthma attacks) or embolisms (cf. Lehmann, 2017, pp. 125–151; Lehmann, 2019b; Heim et al., 2019). Sackeim postulated:

> Several long-term follow-up studies have suggested that patients who receive ECT have reduced mortality of all causes relative to non-ECT control patients. (2017, p. 779)

In his disclosure of conflict of interest, this doctor had to concede:

> Dr. Sackeim has served as a consultant for LivaNova (vagus nerve stimulation), MECTA Corporation (electroconvulsive therapy), and Neuronetics (transcranial magnetic stimulation). In the past, he has also consulted with or received research support from the brain stimulation companies Brainsway, Cyberonics, Cervel Neurotech/NeoStim, Magstim, NeoSync, and NeuroPace and from the pharmaceutical companies Cambridge Neuroscience, Eli Lilly and Company, Forest Laboratories, Hoffman-La Roche, Interneuron Pharmaceuticals, Novartis International, Pfizer, Warner-Lambert, and Wyeth-Ayerst. He is the originator of magnetic seizure therapy and is the inventor on a nonremunerative patent for focal electrically administered seizure therapy. He is also the inventor on a nonremunerative pending patent on titration in the current domain as a method for seizure threshold determination in electroconvulsive therapy. (ibid, p. 780)

Knowing the transfers of values between the health care industry and Dr. Tiihonen or Dr. Sackeim, who postulated respectively that there is a correlation between polypharmacy and dose levels of neuroleptics or electroshock and the prolongation of life expectancy, people can form their independent opinion as to the credibility of such surprising statements.

Even considering the point of view that reduced life expectancy has nothing to do with the adverse and often toxic effects of psychiatric drugs, patients should have full access to all possible information about adverse effects. As demanded by Marina Langfeldt (2017), former senior public prosecutor at the Zweibrücken public prosecutor's office (Germany), regarding the enormous risks and damages in particular of newer antidepressants and neuroleptics (Lehmann, 2017), this information should include unlimited access to specialists' information for patients not only in Switzerland, as is the case today, but also in EU member states. To assess the risks of psychiatric drugs, patients and their confidants should have unlimited access to results of studies and reports on adverse effects on all levels, even if not published (Hengartner, 2019). Access to information sheets on risks and damages of psychiatric drugs and electroshock, as well as alternatives beyond these measures should also be available for patients with intellectual problems or disabilities. The same goes for people coming from abroad, such as the pilot project mentioned in RLP to provide information on neuroleptics (NetzG-RLP, 2018c) and antidepressants (NetzG-RLP, 2018d). In a modern Europe, this information

is also expected in national clinics for people in several foreign languages (NetzG-RLP, 2018e). To assess the independence of HCPs, all people should be able to have unlimited information on the transfers of values between the health care industry and HCPs. The same goes for HCOs also, including patients' organisations. There are organisations, calling themselves 'patients' organisations', but which were founded by the pharmaceutical industry, receiving major financing from them and accepted as advisors by the European Commission. The same is true for organisations of relatives and friends (see Lehmann, 1996, 2009, 2010; Keller, 2005a, 2005b).

Transparency would allow all stakeholders to build an independent opinion about statements coming from HCPs and HCOs once information on the transfers of values between them and the health care industry is readily available. It would enhance the chances for compensation of people who have been damaged by products of the health care industry. In case of a deadly outcome of treatment, there would be a better chance for compensation to the bereaved ones. Monitoring and prevention systems could be improved if transparency is enforced.

## Mistrust in the Health Care System?

The demand for full transparency on all levels is no product of ignorance, mistrust, paranoia, mental disease or conspiracy theory, but is based on the experiences of the lack of transparency and manipulation mentioned above. The result of this is often anything but the best attainable mental health. One of many examples are the thousands of cases of chronic diabetes which occurred after the drug firm Eli Lilly did not disclose their knowledge about diabetes as an adverse effect of their psychiatric drug olanzapine (marketed as Zyprexa and many other names, from Aedon to Oferta to Zyrepin). Due to the lack of information about these risks and damages, which affected many patients, the drug firm in 2005 finally paid $690,000,000 in the USA to settle claims of patients who had received Zyprexa and developed chronic diabetes (Associated Press, 2005; PsychRights, 2006). Here in Europe, class actions are very rare and most often not allowed in this field of health care making it difficult for consumers to take action.

Cooperation with drug firms that perform good research and produce good products should not be a problem in principle. This should be the case for HCOs and HCPs, including organisations of users and survivors of psychiatry. To provide meaningful involvement of users and survivors of psychiatry in all aspects of psychiatric drug issues – especially registration and monitoring of psychiatric drugs – they must be involved in ethics committees, licensing processes, in providing guidelines, and decision-making about effectiveness and reimbursement of costs. Where such conditions do not exist, independent and user/survivor-controlled

research is needed on the best way to achieve independent and user/survivor-controlled education and independent and user/survivor-controlled information about the effects of psychiatric drugs and relevant training programmes must be designed (Lehmann, 2005).

It should also be self-evident, that the health care industry gets paid for their products. On the other hand, intransparency leading to false information for the public, HCPs and HCOs can have a catastrophic outcome, particularly for the most vulnerable stakeholders: the patients, and here particularly, psychiatric patients. They are damaged, they can even lose their health and life. And they will lose their trust in HCPs and HCOs. As a result, they will deny medical assessment and treatment even if it is necessary and perhaps life-saving. HCPs will lose their credibility, and finally the drug firms will lose their credibility, which is already more and more the case and cannot be in their interest. In the end, the public will be full of mistrust because there is the suspicion of conflict of interest. This would be the result if the transfer of values is kept as hidden as it currently is.

For enlightened and self-confident citizens of the 21st century, transparency at all levels of life should be obvious, particularly for patients, whether in the somatic or in the psychiatric field. Seven decades worth of a chance to develop rules of self-regulation by the health care industry now make strong regulations necessary.

## The Right Approach to Ensure Greater Transparency of Cooperation Between the Health Care Industry, HCPs, and HCOs

As a consequence of the previous remarks, the approach to ensure greater transparency of cooperation between the health care industry, HCPs, and HCOs, cannot be stressed enough. Even if national states can develop their own regulations, a European regulation for the strongest transparency possible would be an encouraging signal for all political parties, HCOs and HCPs to develop meaningful regulations in their national states and in their organisations. The EU Commission and other EU agencies could set a starting point and deny funding of HCPs and HCOs which have a demonstrated conflict of interest, at least as long as they do not adopt and implement serious conflict of interest policies and strengthen disclosure policies.

In 2009, the US-American Institute of Medicine (IOM; now called the National Academy of Medicine – a non-profit and non-governmental organisation) published recommendations about conflict of interest in medicine. These recommendations cover many aspects of medical research, education, and practice as well as both individual and institutional financial relationships. Many of their proposals, published by Robert Steinbrook (2009), national correspondent for the *New England Journal of Medicine*, ENUSP adopted verbatim in their

recommendations. (The directly cited passages are not specially marked.) The following list is based on Robert Steinbrook's *Overview of IOM Recommendations about Conflict of Interest in Medicine*, but supplemented with some of my own proposals and with the position of the European Public Health Alliance from 2001 about the independence of patients' organisations:

- Institutions engaged in medical research and education, clinical care, and the development of clinical practice guidelines should adopt and implement conflict of interest policies and strengthen disclosure policies. They and other interested organizations (such as accrediting bodies, health insurers, patients' groups inclusively users and survivors of psychiatry, medicine publishers, medicine journalists, and government agencies) should standardize the content, formats, and procedures for the disclosure of financial relationships with the drug and electroshock industry. All organizations that accept funds from the pharmaceutical and electroshock industry should determine an upper limit to the proportion of industry sponsorship and their total income. They should also articulate clearly the role of the sponsoring body in relation to sponsored projects and to the organisation as a whole in their statutes.

- Parliaments should create national programs that require pharmaceutical, medical device, and biotechnology companies and their foundations to publicly report payments to HCPs and other prescribers, biomedical researchers, health care institutions, professional societies, patient advocacy and disease-specific groups, providers of continuing medical education, foundations created by any of these entities, medical publishers, and medical journalists. Until the parliaments act, companies should voluntarily adopt such reporting.

- Academic medical centers, research institutions, and medical researchers should restrict participation of researchers with conflicts of interest in research with human participants. Exceptions should be made public and occur only if a conflict-of-interest committee, where representatives of patients' organisations, which do not have conflicts of interest relevant to the activities of the institution, are meaningful involved, determines that an individual's participation is essential for the conduct of the research and if there is an effective mechanism for managing the conflict and protecting the integrity of the research.

- Academic medical centers, teaching hospitals, faculty members, students, residents, and fellows should reform relationships with industry in medical education. These institutions and professional societies should provide education on conflict of interest.

- The organizations that created the accrediting program for continuing medical education and other interested groups should reform the financing system so that it is free of industry influence, enhances public trust in the integrity of the system, and provides high-quality education.

- Physicians, professional societies, hospitals, and other health care providers should reform physicians' financial relationships with industry. The same standards should apply to community physicians, medical school faculty, trainees, medical publishers, and medical journalists. They all should forgo all gifts and other items of material value from pharmaceutical, medical-device, and biotechnology companies, accepting only payment at fair market value for a legitimate service in specified situations. Physicians should not make educational presentations or publish scientific articles that are controlled by industry or contain substantial portions written by someone who is not identified as an author or who is not properly acknowledged. Physicians should not meet with pharmaceutical and medical device sales representatives except by documented appointment and at the physician's express invitation and should not accept drug samples except in certain situations for patients who lack financial access to medications. Until institutions change their policies, physicians, trainees, medicine publishers, and medicine journalists, should voluntarily adopt these recommendations as standards for their own conduct.

- Medical companies and their foundations should reform interactions with physicians – for example, by instituting policies and practices against providing physicians with gifts, meals, drug samples (except for use by patients who lack financial access to medications), or other similar items of material value and against asking physicians to be authors of ghost-written materials. Consulting arrangements should be for necessary services, documented in written contracts, and paid for at fair market value. Companies should not involve physicians and patients in marketing projects that are presented as clinical research.

- Groups that develop clinical practice guidelines should restrict industry funding and conflicts of panel members. Various entities, including accrediting and certification bodies, formulary committees, health insurers, and public agencies should create incentives for reducing conflicts in clinical practice guideline development. Existing practice guidelines which were written by participation of HCPs and HCOs in conflict of interest, should be worked over at once by HCPs and HCOs that do not have conflicts of interest relevant to

the activities of the institution. It would be a strong signal by the health care industry if they would take over the costs for developing and publishing the new, independent guidelines.

- The governing bodies of institutions engaged in medical research, medical education, patient care, or guideline development should establish their own standing committees on institutional conflicts of interest that have no members who themselves have conflicts of interest relevant to the activities of the institution.

- The National Institutes of Health should revise federal regulations to require research institutions to have policies on institutional conflicts of interest, including the reporting of identified institutional conflicts of interest and the steps that have been taken to eliminate or manage such conflicts, and also to have a meaningful involvement of representatives of patients' organisations free of conflict in interest in the design, execution, evaluation and publication of the research.

- Oversight bodies and other groups should provide additional incentives for institutions to adopt and implement conflict-of-interest policies, such as by publicizing the names of institutions that have instituted the recommended policies and those that have not.

- Departments of Health and Human Services and their agencies should develop and fund research agendas on conflict of interest.

- There should be common online data bases on conflicts of interest free and easily accessible in all languages based on a template nationally.

Referring to the American philosopher and cognitive scientist Noam Chomsky (2005) from the Massachusetts Institute of Technology in Boston, Giovanni Fava explained the need to defend intellectual freedom and to overcome the dependence from the health industry by an holistic approach:

> The problems caused by the increasing financial ties between the pharmaceutical industry and researchers and clinicians can be addressed only by a complex effort encompassing both the establishment of lines of support of independent researchers who are free of substantial conflicts of interest and better disclosure policies and conduct regulations as to financial ties. Such effort requires a bold shift from current, largely inadequate strategies. In the long run it may entail, however, substantial advantages to patients, clinicians, researchers, the health industry and the civil society at large. (2007, p. 19)

Furthermore, HCPs and HCOs which fail to disclose their conflicts of interest in a correct and complete form should in addition to other measures, be forced by law, to pay money comparable to their profits in a fund controlled by patient organisations that do not have conflicts of interest for support in recovery from treatment damages and for support in withdrawal of drugs in case of dependence, withdrawal and reduction problems.

Reiner Ott, Board member of the German Federal Organisation of (ex-) Users and Survivors of Psychiatry (BPE), responded when asked for his opinion on transparency in the psychosocial field:

> If clinics or doctors openly disclosed their conflicts of interest, their connections or non-connections with the pharmaceutical industry, then I would develop trust faster and easier than if I have no information about those connections at all. For me, the situation is similar to the control lobbies have over politicians. (2019)

Although yet to have binding force, the Association of the British Pharmaceutical Industry has developed together with National Voices, a coalition of health and social care charities in England, a remarkable guide to collaboration between charities and pharmaceutical companies. 'Transparency, including the disclosure of relationships, is vital for ensuring accountability, building trust and maintaining a good reputation', they wrote and referred to their Code of Practice, which

> ... requires companies to publish details about their relationships with patient organisations, to name the organisations, describe the nature of the activity (whether support or contracting for services) and the associated monetary and non-monetary values. (...) Charities should be aware of the risk of appearing to have something to hide. Charities should consider not only what to disclose but how to disclose it. The easier the information is to find, the less likely that someone will complain that the organisation has something to hide. (ABPI & National Voices, 2014, p. 7)

## Conclusion

A European regulation for the strongest level of transparency would be an encouraging signal for all political parties, HCOs and HCPs to develop meaningful regulations in their states and in their organisations. But each commission or agency, on a international or national level, could set a starting point and deny funding of HCPs and HCOs that have demonstrated conflicts of interest, at least as long as they do not adopt and implement serious conflict of interest policies and strengthen disclosure policies. To promote the right to informed consent, patients

and their confidants should have unlimited access to results of studies and reports on adverse effects on all levels, also if not published.

Transparency would allow all stakeholders to build an independent opinion about statements coming from HCPs and HCOs if the transfers of values between the health care industry and them were fully transparent. Monitoring and prevention systems could be improved if transparency is enforced. This would prevent patients from developing diseases due to adverse effects of drugs administered. Absences from work, sick leave and early retirement would also decline, as would medical costs, which would otherwise have to be borne by health insurance funds, the general population, and state health care institutions. Full disclosure of conflicts of interest, based on strong regulations, would enhance the credibility of all stakeholders, drug companies included; it would have a win-win outcome.

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