

How does the pharmaceutical industry do biopolitics?*

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Abstract: The goal of this text is to show how the drug industry does biopolitics. I am trying to describe the actions of the pharmaceutical industry, its strategies as well as its ability to shape modern science and affect medical professionals, to influence state policy and even to form our perception of what diseases are. I distinguish five fields of the pharma-biopolitical influence: its impact on the scientific and medical environment, the impact on governments, the direct impact on drug users and potential clients, the impact on research subjects in drug testing and finally the impact on bioethicists – and I shortly analyze each of these. I am trying to formulate the main ethical challenges that arise from the pharmaceutical biopolitics. This article may serve as an introduction to further study of the pharma-industry ethics.

The main goal of the article is to present a general overview of how the drug-industry does biopolitics. Taking into account the nature of this text, I am using the term “biopolitics” in its broadest

sense and I would like to avoid discussing its meaning. I have given a short account of such debates in the article entitled “Between biopolitics and bioethics”¹. Let us assume that the notion of “biopolitics” stands for all types of policy which focus on biological “life”, especially on the implementation of new biotechnological measures (such as new ways of treatment, new medications or, even more generally, the overall shape of modern science) to achieve political goals (such as influence, power or economic profits).

I will concentrate on two main issues. Firstly, I would like to show where and how the drug-industry develops its policy and who are the main actors of it. I distinguish five fields of the pharma-biopolitical influence. I am going to shortly analyze each of them, revealing some of the conflicts of interest that arise in the process of introducing, promoting and reimbursing drugs. What are those five fields? I distinguish:

- impact on the scientific and medical environment,
- impact on governments,
- direct impact on drug users and potential clients,

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1 „Między biopolityką a bioetyką”, Dialogi Polityczne/Political Dialogues, 17/2014.

- impact on research subjects in drug testing,
- impact on bioethicists.

Secondly, I want to provide an overview of the the main ethical challenges that arise from the pharmaceutical biopolitics. I am going to voice the key moral questions concerning the drug-industry that require appropriate response in the future.

Regarding the character of this text, inevitably, some issues will be only mentioned or underdeveloped – but still, especially for those readers who do not specialize in the drug-industry's ethics, this article may reveal an important aspect of modern biopolitics and it can serve as an introduction for further studies on that matter. Let us move to the biopolitical influence of the drug-industry.

Impact on the scientific and medical environment

How does the drug-industry influence physicians and the wider medical environment? We can distinguish at least three strategies, three different manifestations of this influence. Firstly, I will characterize the activity of the so called REPs - *Pharma Sales Representatives*. Secondly, I will outline the phenomenon of Ghostwriters and Thought Leaders. Finally, I will briefly describe another type of financial influence on science.

Let us start with REPs. In the European Union, unlike in the United States, mass advertising of prescription drugs is strictly prohibited – this kind of ads can be addressed only to the health professionals. The job of REPs is to encourage doctors to prescribe specific drugs. They do it by meeting doctors, entering in friendly relationships with them, recommending drugs, giving educational materials, free drug samples and other gifts.

As one of the former REPs said, “Bribes that aren't considered bribes (...) this is the essence of pharmaceutical gifting.”² The monthly value of reimbursed medicines prescribed by a regular doctor can reach up to seven thousand polish zlotys.³ Specialists give prescriptions for more expensive drugs, so they are even more valuable for the pharmaceutical industry. If a doctor treats chronic diseases, the choice of one particular drug gives a long-term revenue for the drug-producer.

Of course, there are laws regulating this kind of advertisement. For example, in Poland the value of gifts received by a doctor should not exceed one hundred polish zlotys (around 25 euros) and the gift itself should be related to medical practice. How to bypass such regulations? At the Congress of the Polish Psychiatric Association, a company that produces a new drug for schizophrenia organized a contest of knowledge about that drug. Psychiatrists could win a car navigation, alcohol or jewelry⁴. The name of the competition was „Effective without a shadow of doubt”. Could this slogan be a good description of the REPs' influence on physicians?

As Polish sociologist Paulina Polak wrote,⁵ the golden age of *Pharma Sales Representatives* reached its peak in the 90's, especially in Poland. At that time, the lack of regulations governing this practice led to numerous pathologies:

2 *White Coat, Black Hat: Adventures on the Dark Side of Medicine*, Carl Elliott, Beacon Press, 2010, pp. 63.

3 Paulina Polak, *Nowe formy korupcji. Analiza socjologiczna sektora farmaceutycznego w Polsce*, Nomos, Kraków 2011, pp. 102.

4 Decision of Polish General Pharmaceutical Inspectorate from September 2010 - https://www.gif.gov.pl/download/1/4060/repgifpdf-yREKREK_2010-09-08-43.pdf

5 Polak Paulina, *Nowe formy...*, pp. 78 – 140.

REPs had an easier access to the public doctors' offices than the rest of the society and the value of gifts handed to doctors was rapidly escalating. In the 90's, REPs had mainly medical or pharmaceutical education and impressive budgets to allocate. Today, the profession has lost its prestige. Why? The rising expectations of doctors who used to receive significant benefits for prescribing specific drugs made the entire process less profitable. Modern REPs usually do not have any medical education – they are specialists in sales and advertising.

Why is the existence of REPs legal? The rationale for their work is the need to educate physicians and familiarize them with new products. The quality of this knowledge is, however, questionable, regarding the fact that REPs have no interest and even no possibility to deliver objective information to physicians – what they do instead is advertising.

How to hide large sums of money paid by REPs to the physicians? The doctors may receive official contracts for medical consultations or participation in the fourth phase of the clinical trials (to fill in questionnaires about the side effects of a specific drug, which may even be based on non existing patients) but the real sense of the deal between REPs and physicians is clear – the doctor agrees to prescribe a specific drug.⁶

How do REPs know if physicians stick to their contract? In small villages, REPs can rely on their personal contacts with pharmacists in local drugstores. The same way of verification applies to hospital pharmacies. In big cities, REPs may use the services of companies such as IMS Health, which monitor the pharmaceutical market and provide data from pharmacies in a given area. The

salary of a REP depends strictly on his sale effectiveness. A REP knows which doctors are “cheating” (i.e. take money or other profits from REPs but later ignore their agreement and do not prescribe the drugs) and which are not. However, nowadays the activity of REPs is neither the most efficient nor the biggest branch of the pharma-industry's influence on the medical community. A more important phenomenon is the one of Thought/Opinion Leaders and Ghostwriting.

Who are the Ghostwriters and Thought Leaders? Ghostwriters are anonymous authors of scientific literature and educational materials sponsored by the pharmaceutical companies. They may either work in Public Relations agencies or directly for pharmaceutical firms. As Carl Elliot noticed⁷, they tend to be former scientists disappointed with their own carriers. Their job is very similar to the regular scientific work – they analyze, interpret and describe data – but the final goal is to present the results of their research in a positive way, which may obviously lead to concealment, abuse or even hiding of detrimental data.

Ghostwriting is commonly accepted in certain spheres of social life – nobody expects politicians to write their own speeches. However, it is contrary to *the good scientific practice guidelines* expressed in many national and international regulations. What is more, signing and publishing a scientific article written by somebody else may be punished as plagiarism under Polish law. Despite those facts, ghostwriting in medicine does not seem to disappear – for some people, and sometimes for entire companies, it has become the main source of income. The phenomenon of

6 Polak Paulina, *Nowe formy...*, pp. 120.

7 *White Coat, Black Hat: Adventures on the Dark Side of Medicine*, Carl Elliott, pp. 27.

ghostwriting is inherently linked to the existence of the so-called Thought or Opinion Leaders. While ordinary physicians, those who have deals with REPs to prescribe specific drugs, receive in return some additional money, sponsored trips to conferences, trainings, gifts, free lunches or dinners, the Opinion Leaders, associated with drug companies, receive much more money, educational grants, possibilities to conduct clinical trials, invitations to deliver lectures or provide consulting for corporations – all these activities are well-paid and prestigious.⁸

The Thought Leaders are prominent physicians and scientists who decide to cooperate with pharmaceutical firms. They sign the articles written by ghostwriters and give lectures sponsored by the pharma-industry. Thanks to the Thought Leaders, the drug industry influences modern science and education. Nowadays, medical students might listen to a lecture about various symptoms of depression sponsored by a manufacturer of antidepressants. If a Thought Leader works as a director of a hospital, he or she may influence the decisions concerning the medications used in the clinic and determine which drugs or which medical equipment should be ordered. If a Thought Leader works in the civil service as a national or regional health consultant, he or she may recommend specific drugs at an even higher level. For that reason, some amendments to Polish law have recently been considered: from the 11th of September 2014, the advisors to the Minister of Health must disclose their additional earnings and gifts coming from the pharmaceutical companies.⁹

There are also other kinds of the drug-industry's financial influence on science. The pharma-industry conducts studies and monitors data, funds scientific journals or sets up its own, organizes scientific conferences and awards grants to numerous organizations. When *The Hastings Center Report* published the article entitled "Good Science Or Good Business?" (criticizing prescriptions of psychotropic drugs to the patients not diagnosed with clinical depression), Eli Lilly – the manufacturer of Prozac – withdrew its annual donation to the center.¹⁰ The problem concerns not only the publications but also the research itself. Studies funded by the pharmaceutical industry are less critical of new drugs than those sponsored by the governments. "A study by Friedberg et al. (1999) found that 95% of industry-sponsored articles on drugs used in cancer treatment reported positive results, as opposed to 62% of non industry-sponsored articles. (...) Bekelman et al. (2003) reviewed 37 papers on financial relationships and their influence on research and found that there is a statistically significant relationship between industry sponsorship and pro-industry results."¹¹

Is there something inherently wrong with this fusion of industry and science? Not necessarily. Today's science needs money from the private sector, which is its largest sponsor. "Private industry funds approximately 60% of the research and development (R&D) in the United States, while the federal government funds about 35%; 70% of all R&D in the United States is conducted in private venues, followed by federal laboratories

8 Polak Paulina, *Nowe formy...*, pp. 181.

9 Dziennik Gazeta Prawna, "Senat chce ukrócić sponsoring medyków", Beata Lisowska, 2.20.3014, nr 191 (3832).

10 Carl Elliot, *White Coat Black Hat.*, pp. 157.

11 E. Shamoo, D. B. Resnik, *Responsible Conduct of Research*, 2nd Ed. Oxford University Press 2009, pp. 190.

and universities, each at about 15%.”¹²

Vanishing boundaries between information and advertisement are the most worrying aspect of this phenomenon. The pharma-industry has no interest in presenting fully objective data. Truth and profit do not always go hand in hand. As Carl Elliott said: “The concept of shaping the facts runs contrary to the internal ethos of science.”¹³

In the classical Mertonian approach, the ethos of science consists of universalism, communism, disinterestedness and organized skepticism.¹⁴ Is science still a common good now that the research data have become the intellectual property of drug-companies and that they are protected by patent law? Are scientists and physicians able to remain disinterested if they are carrying out research on behalf of the pharmaceutical industry? Can the scientific press remain skeptical while being financially dependent on it? If the collaboration between private industry and science has a long tradition, the character of universities did not change until the twentieth century. “For hundreds of years, universities emphasized academic norms such as openness, free inquiry, and the pursuit of knowledge for its own sake. Business norms, such as secrecy, directed inquiry, and the pursuit of knowledge for the sake of profit, simply were not part of the university culture until the twentieth century.”¹⁵

In recent years, all over the world, a number of regulations were introduced in order to cope with these problems.

12 *Responsible Conduct of Research*, pp. 82.

13 *White Coat, Black Hat: Adventures on the Dark Side of Medicine*, Carl Elliott, Beacon Press, 2010, pp. 38.

14 R.K. Merton, *Social Theory and Social Structure*, New York: The Free Press 1968, Chapter XVIII: Science and Democratic Social Structure, pp. 605-15.

15 *Responsible Conduct of Research*, pp. 84.

Unfortunately, laws and recommendations are usually not effective enough.

Impact on governments

Let us leave science and move to the relations between the drug industry and governments. How can the pharma-industry influence the state? Obviously, it can lobby it into shaping patent law according to the industry’s needs or try to corrupt the organizations responsible for the registration of new drugs, such as, for example, the Food and Drug Administration (FDA) in the United States, the European Medicines Agency (EMA) – in the European Union, or – at the state level – the Polish Office for Registration of Medicinal Products. If a state reimburses certain drugs, there is also space for negotiations of the price – “prices of drugs in countries with free or semi-regulated prices — such as the U.S. — are higher than in countries where more direct forms of price regulation are in place — such as France.”¹⁶

There is a lot of socio-ethical questions concerning the relationship between the pharma-industry and the state. To what extent should the state intervene in the pharmaceutical market? Should the state be a stronger negotiator? Are the current drug prices reasonable? Should patent law be changed?

Let us take a closer look at drug prices. It takes many years to introduce a new drug on the market and the entire process may cost up to one billion euros: “It is estimated that only between 1 in 5,000 to 1 in 10,000 interesting molecular entities will be developed and sold on

16 *Competitiveness of the EU Market and Industry for Pharmaceuticals*, ECORYS Macro & Sector Policies, Client: European Commission, December 2009.

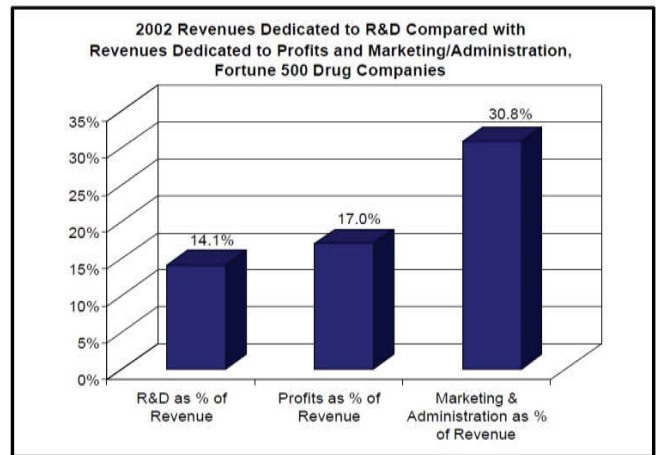
the market.”¹⁷ That is why, the price of a drug consists of the production cost of one particular drug and the cost of all other studies conducted by the company. There is also the cost of advertising, lobbying and the profit.

New drugs are protected by patent law. In the European Union patent protection can last 20 years or more. Of course, patent law affects the prices of medicines. When patent protection ends up, the price of a drug falls even by a half (because now the brand drug has to compete with generics on the market, a generic is a drug with the same composition as the original brand drug).

There is currently a big discussion about patent law and a lot of arguments for and against patent protection are being presented. I will bring up only few of them. First says that the monopoly guaranteed by patent law is a kind of a reward for the risky innovation and that without such monopoly the pharma-industry would have no interest in investing in new drugs (especially for rare diseases). Second argument for patent protection says that it would be unfair if other companies could profit from someone else’s work. The opponents, on the other hand, claim that drugs are not simple market commodities so they should be widely available and cheap – it is hard to compare financial success with the value of life and health.

I understand the potential usefulness of patent law, however, in my opinion, its main problem resides in the scale of profit. What amount of money is enough to be a sufficient reward and incentive? Where is the limit of profit? If “in 2002 profits registered by the 10 drug

companies were equal to more than half of the profits netted by the *entire* list of Fortune 500 companies”¹⁸, then maybe the incentive is too strong? If the drug industry (as it is shown on the graph from 2002, which illustrates also today’s tendencies) spends more on marketing than on research and development, then maybe something is wrong with the entire system.



Source: Public Citizen analysis of company annual reports, *Fortune* magazine, April 17, 2003.

Direct impact on drug users and potential clients

Let us now have a look at how the pharma-industry influences ordinary people. Of course, both the general condition of science and the state policy affect drug users as well, but I will concentrate on methods of direct impact. At this point, we need to remind ourselves of a trivial but important fact: most people profit from the existence of the pharmaceutical industry. Never before in history has medicine been so well developed and we have more and more drugs to cure numerous diseases. In this short chapter, I am trying to show how the drug-industry tries to increase sales of medicines,

¹⁷ *Competitiveness of the EU Market and Industry for Pharmaceuticals*, ECORYS Macro & Sector Policies, Client: European Commission, December 2009

¹⁸ 2002 Drug Industry Profits Report, Public Citizen’s Congress Watch, http://www.citizen.org/documents/Pharma_Report.pdf

regardless of whether they are needed or not.

Advertising is the primary tool. As I mentioned before, the DTC advertising (*direct to consumer*) of prescription drugs is prohibited in the European Union but allowed in the United States. The enormous costs of DTC advertising increase the need for quick profit and make drugs more expensive. At the same time, DTC advertising is very effective. Americans spend the most money on medicines in the world.¹⁹

Apart from mass advertising, there are also different kinds of hidden advertising such as the VNRs and PSAs present in the American television. A *Video News Release* funded by the drug industry looks like other news. It may show a story of a person struggling with a disease, who was cured by a specific drug. It might also concern some disease-awareness events like the World Cancer Day but the goal of a VNR is to promote a drug, not to inform.²⁰

Public-service announcements, funded by the drug industry, have the same objective. Theoretically, a PSA should be constructive and noncommercial, which is why it is broadcasted by the media for free. Pharmaceutical companies, however, use the PSAs for their own purposes, for example, by promoting smoking cessation, they increase sales of nicotine patches. Looking at the consequences of such campaigns, it is difficult to univocally condemn them. The source of moral controversy is rather the intention of advertisers and the fact that they are expanding their promotional campaigns

by using someone else's (in the case of public television – public) money.²¹

Let us leave advertising and move to other PR actions. The drug industry may fund patient associations, or even arrange them, only to use them to lobby governments to reimburse specific drugs. For example, in Poland, diabetes associations inspired by foreign corporations lobbied against the insulin manufactured by Polish companies, despite the fact that Polish insulin is cheaper and of good quality.²²

Another activity of the public relations representatives is the so-called *disease branding*. Simply put, *disease branding* means promoting a new disease (e.g. by using the term *social anxiety disorder* instead of shyness, or the *ADHD* instead of naughtiness – these illnesses do exist but, as a result of *disease branding* and other abuses, they are over-diagnosed, especially in the United States). Disease branding usually follows the same scenario: the goal is to make the public opinion believe that a certain disease is serious, widespread and should not be a cause for shame.²³ Numerous techniques can be used in *disease branding* – such as the described above VNRs, PSAs, social campaigns, lectures given by Thought Leaders, sponsored articles in scientific journals or in ordinary newspapers. The phenomenon of *disease branding* is a worrisome manifestation of the progressive medicalization of life, undermining confidence in the objectivity and beneficence of medicine and

19 *The Global Use of Medicines: Outlook Through 2017*, Report by the IMS Institute for Healthcare Informatics.

20 *White Coat, Black Hat: Adventures on the Dark Side of Medicine*, Carl Elliott, Beacon Press, 2010, pp. 112.

21 *White Coat, Black Hat: Adventures on the Dark Side of Medicine*, Carl Elliott, Beacon Press, 2010, pp. 113.

22 Paulina Polak, *Nowe formy korupcji*, pp. 185.

23 Carl Elliot, *White Coat Black Hat. Adventures on the Dark Side of Medicine*, Beacon Press, Boston 2010, pp. 120.

science. Maybe drug advertising should be even more restricted?

Impact on research subjects in drug testing

There is also another peculiar group of people influenced by the drug industry – the human research subjects²⁴. Every new drug, before it is placed on the market, goes through three phases of testing on humans. The goal of the first phase is to check if the drug is harmless. Therefore, people taking part in the first phase must be healthy – otherwise it would be difficult to determine which health effects are the result of diseases and which are caused by the drug. The second and the third phase of the trial are conducted on people suffering from the disease which the drug is intended to treat. After the drug is approved for sale another, fourth phase of the study takes place – it consists of monitoring how the drug works in a large population. The research subjects from the first phase of the test have only financial interest in taking part in it. They cannot count on being cured because they are not ill. Let us now concentrate on paid research subjects from the first phase of the trials.

To some extent, good health of a research subject is in the pharmaceutical company's interest. Their death could mean the end of the research on the drug and loss of money already invested. On the other hand, it is in the pharmaceutical company's interest that the trials are held as quickly and as cheaply as possible. This leads to morally controversial compromises and risking the health of the "human guinea pigs". Some companies save money by testing drugs in

24 Another problem concerns the policy on animal testing, which I'm not going to deal with because of the scope of this article.

poor conditions on homeless people²⁵ or illegal immigrants. Salaries accepted by homeless people were significantly lower than the common rates found in the industry. As Carl Elliot wrote, SFBC International, the largest private drug testing firm in the United States, conducted trials on illegal immigrants in an overcrowded building not complying with the safety standards and later silenced the participants' complaints by blackmailing them with deportation.²⁶

What is more, in the globalized world the drug testing industry increasingly moves to developing countries, where the regulations governing trials on humans are usually nonexistent (for example, the lack of obligation to obtain informed consent as a prerequisite for a subject's participation in the study) and where people are sometimes willing to take part in the experiment only because it is their sole chance to get any access to medical care.

Usually, the research subjects are poor or unemployed. To choose this form of earning money, they must have a lot of free time (some studies demand a long-term closure in the institution conducting the trial). It is also in the research subjects' interest to receive the biggest pay with the least possible expense of time and health. However, they are not interested in a reliable test result. As they admit themselves, during the trials they are often lying. They lie about their health state and they hide their participation in other drug studies. No one monitors the reliability of the tests carried out on humans, whose bodies are packed with others drugs. And no one monitors the health of those research

25 Carl Elliot, *White Coat Black Hat. Adventures on the Dark Side of Medicine*, Beacon Press, Boston 2010, pp. 145.

26 Carl Elliot, *White Coat Black Hat. Adventures on the Dark Side of Medicine*, pp. 4.

subjects who treat tests like a job and participate in them throughout their life. This situation surely is alarming.

Should drug testing be considered a profession? The status of bio-working and bio-exploitation requires a closer examination²⁷. Some ethicists believe that paying subjects in the first phase of drug research should be prohibited. Such a prohibition, however, would block the entire pharmaceutical industry. What is more, the human subjects themselves are demanding higher salaries for their participation in the studies. According to the ethical recommendations, however, the salaries should not be too high as they may become an offer “one cannot refuse”. The human subjects themselves confirm that for the right price they could even have their leg amputated.²⁸

There is a grain of truth in the Carl Elliot’s perception of this kind of bio-working: „Perhaps there is something inherently disconcerting about the idea of turning drug testing into a job. Guinea pigs do not do things in exchange for money so much as they allow things to be done to them.”²⁹ On the other hand, the current situation is unacceptable. We need regulations that would strike a balance between the individual’s right to make autonomous decisions and the protection against exploitation. Pretending that the paid research subjects are disinterested altruists leads us nowhere.

Impact on bioethicists

Finally, let us move to the relationship between the drug industry and bioethi-

cists. Is there a place for bioethics in the pharmaceutical logic of profit? What role should they play in the process of monitoring the drug industry?

Bioethicists work for the drug industry in many different ways. They may become witness-experts in litigations concerning a pharmaceutical company. They may give lectures sponsored by the industry, write reports and recommendations. They may work in intra-corporate ethics committees or monitor testing on humans in the Institutional Review Boards (IRBs).

Among bioethicists who advise to the pharmaceutical companies are such celebrities as James Childress (for Johnson and Johnson) or Tom Beauchamp (for Eli Lilly). Moreover, many bioethical organizations and journals are funded by the drug industry.

The important question is: should the bioethicists take money from the drug industry? The supporters of such cooperation argue that bioethicists could function as independent consulting firms, whose mission is to control their clients. They may provide some kind of a bioethical audit and paid ethical expertise. However, in contrast to the financial audits, the bioethical recommendations are rarely unambiguous. Apart from monitoring the compliance with the law or with the bioethical recommendations (which professional lawyers are actually better at) the scope of ethical responsibility is not clear. Bioethicists formulate their opinions based on various philosophical or religious assumptions and – most importantly – they are allowed to change their minds. How to distinguish a bioethicist, who changed his or her mind under the influence of new arguments, from a bioethicist, who changed his or her mind under the influence of a bribe? Big corporations of course have

27 Similar problems concern the legalization of other kinds of bio-working such as surrogacy.

28 *White Coat, Black Hat: Adventures on the Dark Side of Medicine*, Carl Elliott, pp.20.

29 *White Coat, Black Hat: Adventures on the Dark Side of Medicine*, Carl Elliott, Beacon Press, 2010, pp. 22.

no interest in hiring bioethicists who will try to block their key projects.³⁰

Working at the university or in the public ethics commission does not guarantee fairness and disinterestedness either. Even if such a committee is not institutionally linked to those whom it should control, it is not rare that its members have individual relationships with the pharmaceutical business. Moreover, studies evaluated by the hospital ethics committees usually are to be carried out at the hospital from which come the evaluators themselves. Therefore, they have a financial interest to accept such a research. Within the state institutions and academics, there are different hierarchies of power which often make accurate and critical approach to the ethical recommendations difficult to achieve.

Controversy over cooperation with big business combines with the broader problem of the so-called CSR – Corporate Social Responsibility. What is CSR – a step in the right direction or a cover-up for the real intentions and irresponsible actions of companies? Some bioethicists argue that the drug industry funds the ethical committees for the same reasons that it supports the charity. Even if the intentions of the corporations are not innocent (ethical advisory bodies within the corporate companies in fact facilitate fundraising and warm up their media image), the positive effects of these actions are real, which is why, according to many bioethicists, it is worth to work with the big business.

In spite of all that, philosophers such as Carl Elliot, claim that bioethicists will not be reliable if they take money from the drug industry and that they should

rather function as external critics than as hired moral experts.³¹

What next?

One of the key notions in the discussion about the drug-industry's biopolicy is the *conflict of interest* (COI). As the authors of the *Responsible Conduct of Research* noted³² – some COIs are inevitable and they are not inherently bad. There is a fundamental conflict of interest in the entire medicine: doctors need sick people to have somebody to cure, does it make them necessarily dishonest?

There are several types of conflicts of interest: COIs might be individual or institutional, real or apparent. Even apparent COIs are dangerous for medicine because they undermine the public trust in science. The general definition of a COI is as follows: “An individual has a conflict of interest when he or she has personal, financial, professional, or political interests that are likely to undermine his or her ability to meet or fulfill his or her primary professional, ethical, or legal obligations.”³³ All the previously described situations – the relationships of Opinion Leaders, bioethicists and the research subjects with the drug industry or the contacts of REPs with ordinary physicians – generate COIs.

There are three ways of dealing with the COIs – disclosure, managing or avoidance/prohibition.³⁴ In my opinion, each COI in the scientific or medical environment should be officially disclosed. Numerous studies have shown that the COIs may affect humans even subconsciously.

31 Carl Elliot, *White Coat Black Hat.*, pp. 170.

32 E. Shamoo, D. B. Resnik, *Responsible Conduct of Research*, 2nd Ed. Oxford University Press 2009, pp. 189 – 207.

33 *Responsible Conduct of Research*, pp. 191

34 *Responsible Conduct of Research*, pp. 194.

30 Carl Elliot, *White Coat Black Hat*, pp. 144.

Of course, there are some exceptional individuals who can remain honest even in situations of enormous temptation, such individuals, however, should not be taken for the basis of the ethical or legal regulations. That is why, each sponsored lecture, conference, educational material or article, should contain a visible disclosure. Some conflicts of interest should be strictly avoided – as it is, for example, in the Polish Council of Transparency, which recommends medications for state reimbursement – its members and even their families cannot have any incomes from the drug industry.

Sometimes, it is difficult to decide whether a given COI should be only disclosed or if it is dangerous to the point that it should be eliminated. In these cases, as the authors of the *Responsible Conduct of Research* rightly claim, the intensity of a given COI should be taken into account with both the consequences of possible abuse and the consequences of the potential prohibition. Maybe in some cases additional monitoring of the research where COIs are likely to appear would be sufficient.³⁵

Regulating science is very difficult – excessive criminalization and suspicion can block its development but, on the other hand, ethical recommendations without any executive power tend to be useless. This is why the entire issue requires further examination.

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³⁵ *Responsible Conduct of Research*, pp. 195.