The importance of “disclosure” in relationships between physicians and pharmaceutical companies

Abstract

The article raises issues of transparency in relationships between doctors and drug manufacturers. It indicates how important it is as a way for physicians and the pharmaceutical industry to regain public trust. The manuscript will define the concept of disclosure. It will discuss in detail The Physician Payment Sunshine Act from the U.S., which imposes a legal obligation on pharmaceutical companies to disclose their relationships with doctors and university hospitals. The article will also show the diverse regulation of disclosure in different countries of the European Union. The situation in Poland will be also described. In the summary, there will be a discussion about the importance of disclosure for patients and the advantages and disadvantages of such regulations for physicians and drug manufacturers.

Keywords: conflict of interest, disclosure, ethical standard, pharmaceutical industry

JEL Classification: I18

1. Introduction

The public is usually informed about the contacts of doctors with pharmaceutical companies by journalists who see different kinds of irregularities in these relations. Doctors and the pharmaceutical industry are often accused of unethical cooperation (Lizut, 2006, p. 4; Rabij, 2014, pp. 32–35). Medics receive gifts from drug manufacturers, go to sponsored conferences and have the opportunity to perform certain jobs commissioned for remuneration. All of this is meant to make them write out prescriptions for specific preparations. Entangled in various dependencies and cooperation with drug manufacturers, doctors may stop noticing that they have faced a conflict of interest, and will not always put the best interests of the patient above the interest of the drug producer. Often, they deny that pharmaceutical companies exert any influence on them (Wazana, 2000, p. 375; Orłowski & Wateska, 1992, pp. 270–271).

Such situations take place not only in Poland but in many countries around the world. Drug manufacturers are usually international corporations which use similar ways of impacting the medical community everywhere in the world (Kruczkowska, 2013, p. 8; Wazana, 2000, pp. 373–380). Most doctors in Poland maintain contacts with the pharmaceutical industry (Makowska, 2010), as is the case in other countries (Campbell et al., 2007, p. 1746; Lieb & Scheurich, 2014; Wazana, 2000, p. 376).

From the points of view of both physicians as well as pharmaceutical companies, information about such relationships reaching society are unfavorable for image reasons. For several years, the prestige of the medical profession in Poland has been lowering. In 1999, in the hierarchy of prestige of professions, doctors ranked second and nurses ranked fifth (CBOS, 1999). In 2013, nurses maintained their position, and doctors fell to the eighth place (CBOS, 2013). In the ranking of trust in a profession from 2016, the doctors were also in the eighth position (just after shop sellers and six places behind nurses) (CBOS, 2016). It is worth noting that in the professional hierarchy nurses are lower and for many doctors the fact of putting them above “better educated” physicians in social research is difficult to understand (Makowska, 2016, p. 96).

Pharmaceutical companies are also severely affected by the various media “reports” of irregularities in their operations. This kind of information is often the result of the interest of the prosecutor’s office in the company (Hajnosz & Wróblewski, 2007, p. 6). It also happens that the journalists conducting the investigation, provoke the interest of law enforcement agencies in drug manufacturers (Szymborski, 2003, pp. A1–A4). It can often end up with a ruling of very high compensation (e.g. Schering-Ploug has been ordered by the US court to pay 500,000 USD fine for violating the Act on Foreign Corruption Practices in Poland) (cf. Makowska, 2012, p. 131). A lack of trust in pharmaceutical companies may lead to public undermining of the safety of their medicines (and thus, among
others, strengthening anti-vaccine movements), questioning the right price of medicines, or the activities of the medications produced by it. This, in turn, may have negative consequences for public health.

Under these circumstances, the “transparency” of the relationship between physicians and pharmaceutical companies became an important concept. This concept means that the public is informed about the cooperation between drug manufacturers and representatives of medical professions, as well as with healthcare organizations (INFARMA, 2015). Their mutual relations should be as transparent as possible to help regain public trust.

The goal of the article is to describe the existing (legal and voluntary) regulations regarding the principles of transparency\(^1\) in the relations between physicians and pharmaceutical companies and the indication of their weaknesses. The article will describe in turn—American regulations, the standards of selected European Union countries, and Polish standards aimed at increasing transparency in the cooperation of medics with drug business. The summary contains conclusions on the importance of these various provisions on transparency for patients, and on the problems and benefits of these for doctors and pharmaceutical companies.

2. Sunshine Act in the United States

The United States pioneered the principles of transparency in the relations between doctors and the pharmaceutical industry. The Physician Payment Sunshine Act (Open Payments), which forms part of The Patient Protection and Affordable Care Act (PPACA, colloquially called Obamacare) from March 23, 2010 obliged the producers of medical devices, including medicines and medical equipment, which participate in federal health programs, to make their relations with physicians and university hospitals become public.

From August 1, 2013, producers of medical products such as medicines are required to collect data and submit annual reports on the doctors they have worked with, and what benefits they have provided to them. In addition, pharmaceutical companies must specify the benefits that physicians have gained from them: gifts; cash (or cash equivalents, e.g. vouchers), items or services, shares on the stock market, payment for consultations, withdrawals for other services, fees, tickets for entertainment events, meals, travels, research works, educational meetings, payments to charities, royalties or licenses, ownership rights or investment interests (present or future), remuneration for delivering papers at CME meetings (continuation of medical education), grants. However, you do not need to report such gifts which had a one-time value which did not exceed 10 USD, and when the total value of these products did not exceed 100 USD in a given calendar year (Agrawal, Brennan & Budetti, 2013, p. 2055). In addition, benefits such as snacks during conferences or educational meetings were excluded from reporting, as well

\(^1\) It should be noted that this term is relatively new. There are no definitions and interpretations in literature, especially in Polish.
as drug samples, educational materials for patients, short-term medical equipment rental for evaluation purposes, services which are used under the guarantee after purchase or during the leasing of medical equipment, price cuts, materials that a doctor gets when he is a patient, items used to provide charity care, dividends and other forms of profit distribution, doctor’s remuneration for non-medical activities (e.g. legal advice when he is also a lawyer) (American Medical Association, “Sunshine Act FAQs”).

Not all healthcare professionals who have contacts with industry must abide by these transparency rules. Manufacturers must report data on: physicians, osteopaths, podiatrists, dentists, oral and maxillofacial surgeons, ophthalmologists, chiropractors. However, they do not need to report on the actions taken for the benefit of, for example, nurses or medical assistants.

Information on cooperating doctors is provided to the Centers for Medicare and Medicaid (CMS), within the prescribed period. In addition, the Sunshine Act requires that this data be reliable and complete. If the drug manufacturers fail to meet their obligations, a fine is imposed on them. Physicians should receive information from the company that will be published about their person, at least 45 days before their transfer to CMS, because they must be able to report any comments on the data (Agrawal, Brennan & Budetti, 2013, p. 2056). American Medical Association even offers a special application to doctors that helps them track the benefits, which companies report that they gave them.

The Sunshine Act aimed to ensure transparency of relations between companies and physicians. Any interested patient can check if his doctor cooperates with a given pharmaceutical company. All you have to do is go to the cms.gov website, where all data provided by pharmaceutical companies are disclosed. Complete information on the doctor is also published there (AdvaMed, n.d.). It should be emphasized that the Sunshine Act is not aimed at forbidding the relationship between physicians and producers, but: 1) talking about public concerns about the doctor-company relationship and collect data on this cooperation; 2) helping the relations between them be clear and transparent; 3) providing a unified system for collecting data on the financial side of this cooperation; 4) ensuring that the collected data is reliable; 5) preventing unfair influences on research, education and clinical decision making; 6) preventing conflicts of interest, which may affect patients and the care exercised over them (Centers for Medicare & Medicaid Services, “Fact Sheet for Physicians”).

Sunshine Act from the beginning has been criticized for the fact that it will be difficult to get full data in these reports, it was especially a problem when information was being collected. Some of the benefits for doctors remained hidden (Belluz, 2014). Similarly to those received by the people related to medical care and not subject to disclosure (e.g. nurses). Doctors were also concerned whether the data which companies reported were appropriate or not. Sometimes they lose their precious time explaining irregularities. The research conducted in 2012 in those states in which transparency was previously introduced indicates that this

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2 Nurses in the US can prescribe prescription drugs.
legislation had little impact on prescriptions prescribed by doctors, and had no impact on drug costs paid by patients (Pham-Kanter, Alexander & Nair, 2012, p. 819).

A collective report on the benefits provided by companies to US physicians (Open Payments) from 2015, indicates that 1,456 pharmaceutical companies have transferred some services to 618,000 doctors and 1110 university hospitals. The companies that provided some benefits in 2015 were 7.8% less than in the previous year, the number of doctors remained unchanged, and the number of university hospitals decreased by 2.2%. In 2015, companies donated general benefits worth 2 billion USD to doctors, and 86.39 million USD for medical examinations. University hospitals received 605 million USD of general benefits, for research—724 million USD. In general, the companies spent 3.89 billion USD on research (Centers for Medicare & Medicaid Services, 2016). Novartis reported the largest benefits transfer spending 539 million USD, 95% of which was intended for research funding (PolicyMed, 2016). The specialists best-paid by the industry were those dealing with nuclear medicine (on average they received support of 51,279 USD), then neurosurgeons (26,064.33 USD) and orthopedic surgeons (26,080.31USD) (The CMS Blog, 2016).

3. Transparency in European Union countries

The enforcement of the Sunshine Act in the United States has led to public debate on such solutions. In particular European countries, similar regulations have been established. On this basis, you can distinguish the countries: 1) which introduced solutions in the law similar to those in the USA (e.g. France, Portugal and Slovakia), 2) countries where there are not very restrictive regulations regarding the disclosure of links with the industry (e.g. Belgium, Denmark, Germany, Spain, Italy) and 3) countries where there are only voluntary codes, which the European Federation of Pharmaceutical Industries and Associations (EFPIA) is responsible for.3

Detailed information on solutions operating in individual countries is presented in Table 1.

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3 We do not discuss the EFPIA code in this place, because in Poland INFARMA implements it as a “Kodeks Przejrzystości” [“Transparency Code”] and it was described in detail in point 4.
Table 1. Individual countries of the European Union and their activities for transparency in the relations between a physician and a pharmaceutical company.\(^4\)

<table>
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<tr>
<th>Country</th>
<th>Characteristic features / description</th>
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| France  | • the law governing transparency has been in force since the end of 2011;  
• pharmaceutical companies must disclose contracts with health professionals and healthcare organizations and material or monetary benefits in excess of 10 Euros;  
• this data must be made public on a special website at an appropriate time twice a year;  
• fines and sanctions will be imposed on enterprises that will evade the obligation to publish data (45 thousand EUR for deliberate non-publishing of data in the case of medical professionals, and 225 thousand EUR in the case of concealing cooperation with healthcare organizations);  
• in France, there is also the LEEM Association, which implements the Disclosure Code regulation on behalf of EFPIA; |
| Portugal| • the law setting out the transparency rules has been in force since 2013;  
• pharmaceutical companies must disclose contracts concluded with representatives of medical professions and healthcare organizations as well as material or financial benefits exceeding 25 EUR (in October 2014 this amount was raised to 60 EUR);  
• regulations also cover any natural or legal person, referred to in the regulation, involved in the production process, including the authorization holders of allowing a given product to be marketed;  
• pharmaceutical companies are required to keep records of documents relating to each of the events directly or indirectly sponsored or organized in the last five years and made them available to the legal institution, i.e. INFARMED. Violation of these rules is punishable by a fine;  
• in Portugal, there is also the APIFARMA Association, which implements the Disclosure Code regulation on behalf of EFPIA; |
| Slovakia| • the law setting out the transparency rules has been in force since 2011, the amendment entered into force in 2016;  
• previously, pharmaceutical companies had to submit an annual report to the Ministry of Health, stating the value of expenditure on advertising and marketing and other benefits provided to representatives of medical professions in a direct or indirect way. The report must contain beneficiaries’ data and the amount of expenses;  
• since 2016, the obligation to report on benefits for doctors and health organizations twice a year has been introduced. What you need to report is more detailed than the data required by AIFP, an association of companies implementing Slovakia’s Disclosure Code on behalf of EFPIA; |

\(^4\) It should be noticed that legal regulations in individual countries are constantly changing and the data presented in this article may need to be updated.
### Denmark
- The law setting out the transparency rules has been in force since the end of 2014;
- Drug manufacturers and manufacturers of medical equipment are required to report once a year all connections they have with doctors;
- The main obligation to disclose benefits lies with the representatives of the medical professions who must obtain approval from a specially appointed institution (Sundhedsstyrelsen) before they can cooperate with a specific pharmaceutical company;
- In Denmark, there is a LIF association that implements Disclosure Code on behalf of EFPIA;

### Greece
- The law setting out the transparency rules has been in force since the end of 2014;
- Pharmaceutical companies must disclose all services to physicians and other listed persons on their websites and EOF’s official websites (Greek National Drug Administration) no later than 6 months from the end of the calendar year;
- There is no need to spread information about market research, meals and drinks, as well as benefits of a minimum value (defined at 15 Euro), which serve the professional practice of a physician;
- In Greece, the SfEE Association operates, which implements Disclosure Code on behalf of EFPIA;

### Romania
- The law setting out the transparency rules has been in force since 2014, additional regulations were also introduced in 2015;
- Pharmaceutical companies operating in Romania must disclose all “sponsoring” activities for doctors, nurses, health organizations and patient organizations to the Ministry of Health and the National Medicines Agency;
- Persons who have received a benefit from a pharmaceutical company must also report it;
- ARPIM operates in Romania, an organization which implements Disclosure Code on behalf of EFPIA;

### Countries where there are not very strict regulations

### Belgium
- Pharmaceutical companies are required to report information on the benefits received by medical professionals to a special institution (AFMPS) by March 1 each year;
- Pharmaceutical companies must maintain data with detailed information on gifts, benefits, financial support and payments for services that are received by healthcare professionals;
- Drug manufacturers must meet specific requirements prior to launching new products or sponsoring scientific events. Failure to meet these requirements may result in a fine or imprisonment;
- There is also an association called pharma.be in Belgium which implements the Disclosure Code regulation on behalf of EFPIA;
### Germany
- German legislation imposes quite general information obligations on the pharmaceutical industry;
- The Medical Devices Act (Arzneimittelgesetz) imposes information obligations in relation to research conducted on medicines in order to collect knowledge about the safety of approved or registered pharmaceutical products;
- representatives of medical professions cooperating with pharmaceutical companies are almost always obliged to disclose these connections to their employers or principals (*the doctrine of employer consent*);
- the German FSA implements the *Disclosure Code* regulation on behalf of EFPIA;

### Spain
- pharmaceutical companies must publish details of the benefits they have given to health professionals and healthcare organizations (e.g. conferences, congresses, study tours).
- financed conferences and publications must contain an indication of the source of financing and the amount of funds allocated by specific entities.
- pharmaceutical companies are required to notify relevant public authorities about their participation in materials (e.g. containing information about medicines) provided to representatives of medical professions. Such materials include scientific journals, books, blogs or other similar publications issued in paper form or by any audiovisual and electronic media;
- Spanish Farmaindustria implements the *Disclosure Code* regulation on behalf of EFPIA;

### Italy
- pharmaceutical companies that manufacture, trade or commercialize medicines on the Italian market are required to inform the Italian Medicines Agency (AIFA) of their intention to organize or fund events related to the commercialized product;
- events not organized in accordance with the law can be canceled by AIFA, and pharmaceutical companies can be punished;
- Italian Farmindustria implements the *Disclosure Code* regulation on behalf of EFPIA.

### Countries where exists only industry self-regulation

#### Netherlands
- in the Netherlands there is no statutory obligation for pharmaceutical companies to publish information on the benefits provided to healthcare professionals and healthcare organizations;
- The Dutch Nefarma Association implements the *Disclosure Code* regulation on behalf of EFPIA;

#### Sweden
- there is no obligation for pharmaceutical companies to publish data in Sweden;
- there are some indirect regulations such as the act on medicinal products or anti-corruption laws based on the penal code;
- in Sweden, there is the LIF Association, which implements *Disclosure Code* on behalf of EFPIA;

#### Great Britain
- currently British law prohibits offering, providing or promising benefits (to promote medicinal products) to medical professionals or suppliers of such products;
- ABPI implements *Disclosure Code* on behalf of EFPIA in Great Britain;
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Poland

• currently in Poland there is no law requiring transparency;
• however, visiting doctors during working hours by medical representatives is not allowed, as well as giving presents whose one-off value exceeds 100 PLN, which are not related to medical practice;
• INFARMA implements the Disclosure Code regulation on behalf of EFPIA;


4. Polish regulations regarding the transparency of the relations between doctors and pharmaceutical companies

So far in Poland, there is no legal solution that would enforce transparency in the doctor-medical representative relationship. Drug manufacturers associated in INFARMA (Association of Employers from Innovative Pharmaceutical Companies) have signed a voluntary document—“Code of Transparency”—which defines the rules concerning the sharing of information on cooperation between drug manufacturers, both representatives of medical professions and healthcare organizations.

The Code is not a Polish idea, but rather a part of the project of the European Federation of Pharmaceutical Industries and Associations (EFPIA), to which INFARMA belongs. Currently, 41 companies that operate in Europe are signed under the code (INFARMA, 2016). The “Code of Transparency” was created at the initiative of the pharmaceutical industry, which considers it necessary to introduce transparent rules of cooperation between companies and representatives of medical professions. Thanks to this, the public will know the real dimension and importance of this cooperation for the health care system, the development of medicine and the well-being of patients (INFARMA, 2016).

The preamble of the Code emphasizes the importance of cooperation between pharmaceutical companies and the medical community, and at the same time it has been pointed out that the public has the right to full information on what this cooperation looks like. It is worth noting that the Code deals not only with doctors, but also representatives of other medical professions such as: dentists, pharmacists, hospital attendants, nurses, midwives, laboratory diagnostics, paramedics or pharmaceutical technicians, as well as cooperation with healthcare organizations (e.g. hospitals, clinics, foundations or universities).

Code signatories must collect the following information: costs incurred in connection with events (various types of educational, promotional or scientific meetings, with the division into registration fees and travel and accommodation costs), remuneration for services provided to the company (divided into remuneration and additional expenses), and services related to research and
scientific activity. A separate subsection in the Code is devoted to information that needs to be collected about cooperation with healthcare organizations.\(^5\)

Companies collect information on an annual basis (consistent with the calendar year) and publish it on their website up to six months from the end of the year. The data must be available for the next three years from the date of making it available, and the documentation regarding the transfer of the benefit must be kept for five years.

Disputes resulting from the application of the Code and cases of its violation are considered by the Disciplinary Court. The Court may apply penalties for delay in providing information by the Signatory. Annexes to the Code are two forms, which are a model for the Signatories in what form and what data should be made available.

According to the “Transparency Code”, the doctor’s identification data (name and surname, place of work, type of service he received from the company and the amount of remuneration he has received from the manufacturer in one year) is only published if he/she gives his/her consent. If he/she does not, then the data concerning him/her will be added to the aggregated data. Therefore, the public will be informed about the relationship between the pharmaceutical company and doctors, but only those who agree to disclose such information. Therefore, this information will not be complete.

Additionally, it is worth paying attention to the limitations that the Code introduces to the registered benefits. There is no obligation to create documentation for benefits related to OTC drugs (over the counter), gifts (up to 100 PLN, related to medical practice or having an educational or informational character\(^6\)), meals (the cost of which does not exceed 200 PLN per person), samples (4 samples of one product can be transferred in a year), discounts and rebates, as well as other commercial tools that are customarily used in the sale of medicinal products (cf. art. 5 point 2 „Kodeks Przejrzystości” [„Transparency Code”]). Thus, the entire area of benefits that can be obtained remains “hidden”.

This makes us ask: why do some companies (Signatories of the “Transparency Code”) publish selective data (indicated in the “Transparency Code”) regarding some doctors (who give their consent)? Such self-regulation of industry is first of all a good “marketing gimmick”—the “Code of Transparency” has been widely discussed in the Polish press and the Internet, and secondly it aims to “protect” against the introduction of legal regulation—e.g. similar to the American or French Sunshine Act and forced to publish all data indicated by law on all physicians who work with companies.

Despite this critical approach, it should be stressed, however, that since we do not have any legal regulations regarding transparency, the publication of data on the benefits provided by the signatories to the beneficiaries by INFARMA is a very important step forward in improving the ethics of cooperation between

\(^5\) Described in more detail: art. 9 „Kodeks Przejrzystości” [“Transparency Code”].

\(^6\) The record regarding gifts is more extensive and contains several exclusions. More on the subject: in art. 38 paragraph 2 and 3 of the “Kodeks Dobrych Praktyk Przemysłu Farmaceutycznego” [“Code of Good Practice of the Pharmaceutical Industry”].
pharmaceutical companies, and representatives of medical professions and health care centers in Poland. The list published by INFARMA in June 2016 is the first such list available to all interested parties, and although it certainly does not show the “full picture” of the relationship, it shows some part of it.

The report distinguishes three groups of “expenditures” of drug manufacturers: for healthcare professionals, for healthcare organizations and for research and development activities. Benefits for healthcare professionals amounted to 17% (107,646,032 PLN) of total benefits, these for healthcare organizations accounted for 20% of all benefits (128,950,676 PLN). The largest amount of funds, as much as 63% (395,533,983 PLN) pharmaceutical companies spent on research and development activities.

Among the types of benefits for medical representatives, the majority (61%) were costs incurred in connection with events, and the part of remuneration for services rendered was 39%. In the case of services for health care organizations, the majority of funds were transferred to costs incurred in connection with events (45%) and donations (41%). The rest (14%) were transfers that were remuneration for services rendered. Reports also include the average value of provided benefits. On average, the health care organization received from the company support in the amount of 32,514 PLN, and representatives of medical professions received an average of 2,772 PLN (INFARMA, 2015–2017). Only 22% of physicians agreed to publish data about their person with the required data (including surname) in individual reports. While, among organizations, as many as 70% agreed to full identification. It should be emphasized once again that these are data coming only from innovative pharmaceutical companies that are signatories of the “Transparency Code”.

5. Conclusions

Research clearly indicates that the benefits from drug manufacturers influence the prescriptions that medics prescribe to their patients (Halperin, Hutchison & Barrier Jr, 2004, p. 1479; Orlowski & Wateska, 1992, pp. 270–271; Wazana, 2000, p. 375). Patients are alerted about potential conflicts of interest in which doctors may find themselves by working with the pharmaceutical industry. This in turn raises their concern about whether the drug therapy prescribed for them is really the best for them. Patients deserve to know if the doctor who treats them has any connections with the industry and if it could have any effect on their therapy. All actions (legal and self-regulatory) undertaken for the purpose of greater transparency of relations between physicians and pharmaceutical companies should be
positively evaluated. Although, certainly, those introduced in the law give a more complete picture\(^7\) of what cooperation between physicians and pharmaceutical companies looks like.

The premise underlying transparency is that doctors will not cooperate with the pharmaceutical industry, which they could later be ashamed of in front of their patients or in the medical community. Of course, when a physician has to agree to the publication of data (in the case of voluntary, and non-statutory regulations), it won’t have such an impact. For if he/she is ashamed of any relationship, he/she will simply refuse to make the information about it public.

The benefits of these regulations for doctors and industry are primarily the ability to avoid further accusations of a lack of ethics in cooperation, which will allow them to rebuild a good image and society’s trust. However, these regulations also raise many problems: doctors giving up cooperation with companies often get rid of an additional source of income, which may arouse their opposition and unwillingness to such regulations, especially in countries such as Poland, where a doctor’s salary is lower compared to other countries in the European Union (Makowska, 2016, p. 46). For pharmaceutical companies, these regulations mean less opportunities to influence the medics with the help of various benefits and the rule of mutuality (more in Ciadini, 2003, p. 33). Doctors may also be concerned about whether data collected and shared by companies are reliable. On the other hand, companies are obliged to collect and accumulate data that they did not have to save.

Transparency (even legally introduced) is not enough to make relationships between physicians and pharmaceutical companies truly ethical. It should also be emphasized that ethical issues have a very wide scope and are not limited to publishing the benefits that physicians gain from cooperation with pharmaceutical companies. They also refer to the reliability of information provided to medics by companies, the honesty of research conducted during this cooperation, as well as many other aspects.

References


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\(^7\) Because they oblige all companies to disclose data and introduce more severe sanctions for their unreliability.
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