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Liability for Damages Caused by COVID-19 Vaccination

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Abstract:

Purpose: *The article discusses the problem of liability for damages relating to optional COVID-19 vaccinations conducted in Poland. The author investigates instances of liability tied to particular entities involved in the vaccination process. First, the liability of the State Treasury based on Government officials promoting the vaccinations in the media. Second, liability of the Material Reserve Agency (now the Governmental Strategic Reserve Agency) for purchasing vaccines as aiding a tort. Third, that same agency held liable - as the importer - under product liability. Fourth, the National Health Fund, liable as the direct organizer of the vaccination. Fifth, the vaccine manufacturer in the context of dangerous product liability. Sixth, the treatment provider liable for the conduct of its personnel. Seventh, the European Union in its capacity as an importer of vaccines, for aiding a harmful effect on one's health, but also for causing damage legally (in two alternative options). The study examines the possible implications of damages for mass vaccination against COVID-19, conducted in Poland from December 2020.*
Design/Methodology/Approach: *The author applies a dogmatic method, examining potential liability due to the different categories of debtors involved in the organization and execution of the vaccination.*
Findings: *Vaccination liability in tort is possible in the situations identified in the article. The main difficulty lies in the necessity of proving at least a condition sine qua non-type of causal connection between vaccination and bodily injury or a deterioration of health. Under this condition, liability may arise on the part of the National Health Fund, but also on the part of the vaccine manufacturer and the European Union.*
Practical Implications: *The conclusions can be used in lawsuits in the event of vaccine-induced harm.*
Originality/Value: *The issue of tort liability for vaccination that is not obligatory but organized by the State has not been extensively studied in the Polish legislation.*

Keywords: *Vaccination, personal injury, tort liability, liability for dangerous product, National Health Fund, State Treasury.*

JEL classification: *K13.*

Paper Type: *Commentary note.*

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1. Introduction, Literature Review, Discussion and Conclusions

There is an ongoing debate in the media regarding potential liability for the side effects of vaccinations that began in Poland on December 27, 2020. Many arguments worthy of further consideration under the law of liability for damages have been raised in this debate. These vaccines are popularized by the Government as well as quite a number of physicians, including epidemiologists. Let me note in advance that the following remarks, which are by their nature quite general, leave aside the variety of types of vaccines that are already in use or will be in use in the near future. The aim of these remarks is to determine whether or not and who can be held liable for the remote temporal effects of health damages causally connected with vaccination.

In any action for damages, it is necessary to identify the injurious event. In this case, it would be the vaccination carried out in accordance with the art, that is, with the state of medical knowledge at the time the vaccination was administered. I exclude from the scope of the discussion cases of technically defective execution of the vaccination itself, as well as the use of vaccine that is not fit for use due to improper transportation, storage, expiration, etc. These, of course, may also be sources of liability, but are not the subject of this analysis. Likewise, I do not engage in a detailed analysis of the elements of injury covered by the remedy, listing only in section 2 their possible categories. This paper does not deal with the idea of statutory changes (Bączyk-Rozwadowska, 2015), but with the law currently in force.

It should also be noted at the outset that, as far as adverse reactions described in the package leaflets are concerned, it is assumed that they are not the responsibility of the manufacturer. With of one the vaccines, the package leaflet indicated itching, headache, transient trigeminal nerve paralysis and severe allergic reactions (Uchańska, 2020). This is a case of the patient acting at his own risk (Kaliński, 2019), which excludes liability for damages, whether by contract or by tort law (Stoll, 1956; 1961). It is, however, difficult to expect that descriptions of adverse reactions distant in time from the use of the vaccine would currently be included in the package leaflets, since this would have no basis in the material collected so far in the course of relatively short-term studies.

We assume that a person who was vaccinated has subsequently experienced some bodily harm or rather a health disorder that he/she believes to be the result of the vaccination. He/she therefore raises claims for non-material damage by way of pecuniary compensation, as well as claims for the coverage of pecuniary damage, covered by Article 444 of the Civil Code (The Civil Code of 23 April, 1964; Journal of Laws 2020, item 1740*)*. In addition, I can imagine that in case of death of a vaccinated person, claims for compensation will be filed by the persons indicated in Article 446 of the Civil Code. In this type of case, in addition to proving the fact of vaccination, which should not present many difficulties, since the records are kept

by the vaccinating units,[2] it is also necessary to determine the responsible entity. There are several categories involved: The State Treasury, the National Health Fund (NHF), the Material Reserves Agency (MRA),[3] a medical unit where the vaccination was performed, finally the person performing the vaccination, and from the distribution chain, the manufacturer and the importer, which also included the MRA.

Particular attention will be given to the potential liability for the vaccine purchase and market authorization release by the EU authorities. Consideration will therefore need to be given to the basis for potential liability to be imposed on each of them.

In order to bear liability on the basis of Article 417 et seq. of the Civil Code, The State Treasury should act in an unlawful manner. Since it is not the organs of the State nor entities which the State is responsible for, have carried out the vaccinations, liability would have to be based on assuming that the media campaign in which Government members promoted the idea of using vaccinations, was actually a harmful act.

Strictly speaking, such behavior is not an unlawful act, which precludes the imposition of liability. It could, however, constitute a kind of incitement to such an act (Article 422 of the Civil Code), but only if it turned out that the vaccine had properties that rendered its use unlawful.[4] The question of these properties will come up again. For the time being, however, it should be noted that incitement can be committed only through intentional guilt. As I believe, for legal qualification of a given behavior as incitement, it is necessary that the instigator had had awareness of illegality of the act he induced. The problem, however, is that according to the state of knowledge from the period in which the use of vaccinations was promoted, there has been no data disclosed to justify concluding such unlawfulness. Indeed, vaccinations are considered safe. It would therefore be difficult to argue reasonably that the vaccination promotional campaign constitutes a case of incitement to an unlawful act, at least as regards the period during which there was no knowledge of the harmful effects of the vaccine. Until such knowledge is acquired by the persons promoting vaccination (not only, of course, by those in Government), the general

[2]*The National Health Fund (NHF) as the organizer of the National Vaccination Program is probably also in possession of such records. It is characteristic that this program is not a source of law within the meaning of Article 87 of the Polish Constitution. As a resolution of the Polish Council of Ministers it does not act pro foro externo, i.e., outside the state administration. This is because it is not a legal act, in particular one issued on the basis of Article 4.1 of the Act of 5 December 2008 on prevention and combating of infections and infectious diseases in humans (hereinafter: the Act on prevention...).*

[3]*From February 8, 2021 – Governmental Strategic Reserves Agency (GSRA), according to the Strategic Reserves Act of 17 December 2020.*

[4]*The unlawfulness of the injurious conduct here would have to be deduced from the unlawfulness of the effect in the form of a health impairment. Although the Polish literature does not address these subtleties, the issue is important because the unlawfulness of the effect does not always indicate the unlawfulness of the injurious conduct.*

claim of incitement is not justified due to the absence of guilt involving the unlawfulness of the vaccination, i.e., lack of action induced by these persons.

The second potential debtor identified above is the National Health Fund (NHF). In this case, a harmful act could be traced back to the execution of vaccinations and the distribution of the vaccines. Since there is no contractual relationship between the patient and the NHF, only tort liability may be considered. This is due to the fact that the NHF's obligation to provide services is not a commitment that binds it to a specific patient. Only a breach of such a relationship could result in contractual liability of the NHF towards the patient (under Art. 471 of the Civil Code). The National Health Fund, which concludes contracts with beneficiaries on behalf of patients (Article 393 of the Civil Code), does not become, based on these contracts, a debtor of the patient. Therefore, there are certainly no grounds to assume contractual liability.

On the other hand, within the tort liability of the National Health Fund towards the patient, the base obligation on the part of the National Health Fund to provide benefits to patients, which results from universally binding regulations, needs to be resolved first. According to article 27 paragraph 1 point 7 of the Act of 27 August 2004 on health care services financed from public funds (the Act of 27 August 2004), the execution of preventive vaccinations constitutes a case of services aimed at the preservation of health, prevention and early detection of diseases. Art. 97, par. 3, point 2 of the Act states that one of the NHF's tasks is to conclude agreements on the provision of health care services, which certainly include the administration of vaccinations. The Act defines health care services (article 5 point 34) as, among others, those which in turn include (article 5 point 40) activities aimed at prevention or preservation of health. The universally binding and statutory nature of these provisions does not raise any doubts.

However, one may wonder to what extent the obligations arising from these provisions are of a public law nature, forcing one to assess the infringement and its consequences in the *imperium* sphere (Article 417 et seq. of the Civil Code), or of a private law nature, justifying liability on general principles (Article 415 et seq. of the Civil Code).

I am in favour of the opinion that although the agreement on the provision of health services concluded by the NHF with the service provider (article 132) (Banaszczyk, 2020) is rather of a civil law nature (although this is not an obvious issue) (Banaszczyk, 2020, p. 1225=, the very relationship arising from the Act of 27.8.2004 and linking the patient with the NHF is of a public law nature and is not a civil law obligation.

It is referred to in the literature as a health insurance relationship (Banaszczyk, 2020)[5]. In particular, it does not result in claims of the patient against the NHF that can be pursued in court (Article 1 of the Code of Civil Procedure) (Banaszczyk, 2020). This is supported, among others, by its compulsory character and the supreme character of the position of the NHF in relation to the patient. Thus, we are not dealing here with a civil law obligation arising by virtue of a statute, but with an obligation arising from the provisions of commonly binding law (Kaliński, 2019).

Therefore the NHF's participation in the administration of vaccinations and distribution of vaccines can only constitute a basis for tort liability and that within the scope of *imperium* (Bączyk-Rozwadowska, 2020, p. 78, note 37 and p. 91) and not *dominium* (Drozdowska, 2014, p. 100)[6]. Compensatory liability of this entity requires unlawful behaviour. Its basis is Article 417 § 1 of the Civil Code. In case of suing the National Health Fund it would be necessary to prove, however, apart from the unlawfulness[7], also damage and an adequate causal link between the harmful event in the form of administering vaccinations and the compromising the health of the directly aggrieved party.

The condition of an adequate causal relation is - at least in the present state of knowledge and except for the cases of undesirable vaccine adverse reactions (VAR) a very difficult link to prove. It must be shown that a vaccination process has increased the probability of placing one's health in danger as opposed the situation with no vaccination administered. It is a matter of statistical regularity, indicating an increased probability of pathological conditions of a certain type (e.g., thrombocytopenia**,** strokes). Such findings generally take a long time, especially if conditions of this sort do not occur until many years after the vaccination. In any

[5]*Considers this relation as belonging to the social insurance law, but due to the lack of court proceedings - in contrast to the social insurance, it should rather be qualified as a health insurance relation.*

[6]*In the literature, however, an opinion is also expressed that non-compulsory vaccinations do not constitute an activity within the scope of imperium, which means that the possibility of applying Article 417 et seq. of the Civil Code to their consequences is excluded. Drozdowska The author on p. 101 et seq. points out, however, that providing the population with protection against infectious diseases has the nature of a public task. This in turn supports the qualification of separately recommended preventive vaccinations (in the sense of article 19 of the Act on prevention) as public tasks as well. It is characteristic that vaccination against Covid-19 was not even included in this group of vaccinations., In my view, however, this does not mean, that the organization of vaccinations does not constitute a public task in this case. This is evidenced by the fact that vaccines are excluded from normal civil circulation and are administered only by the State and its agencies. Clearly, what we are dealing with here is the exercise of powers by the State against a citizen which are stronger than those of ordinary persons, and this is how public authority is defined. Drozdowska, 2014, p. 102. Bagińska, E. 2010. In: System Prawa Administracyjnego, vol. 12, Warsaw, p. 244.*

[7]*The distinctions in footnote 6 are fully valid here.*

case, I am not referring here to VAR, since these are relatively easy to grasp - as they generally take up to four weeks after vaccination to appear.

Longer-term effects on various organs require many years of observation. They can lead to conclusions about a very slight increase in the probability of damaging one's health or placing one's life at risk - in comparison with the non-vaccinated individuals. The finding of a stroke pattern up to 15 years after vaccination in one person's system among a million vaccinated individuals is sufficient in this case (II CSK 364/12, 2013; Bagińska, 2013, p. 104). The German jurisprudence assumes adequacy here and this position is, as I believe, absolutely correct. For evaluating adequacy, it corresponds to the all knowledge available to the courts at the time of ruling and not only that available to the debtor at the time of the injurious act (I ZR 31/51, 1951). An exceptional medical phenomenon such as death of a person from cancer causally linked to a compulsory typhoid vaccination, can be regarded - like the Sèvres standard metre model - as an expression of the position within the system in which the concept of adequacy was created. In expert reports, however, effects that occur very rarely are generally disregarded as allegedly unrelated to the injurious event (Chowaniec and Chowaniec, 2007), which altogether must be viewed very critically.

The question of an increased probability is the question of substantive law. However, it must be proven – as a premise of liability. In terms of this proof, Polish jurisprudence strongly supports the aggrieved party. This is possible because court evidence is psychological in nature, not logical (Malinowski, 2002) in the sense of the plaintiff having to prove the elimination of causal connections other than those covered by his claims. Thus, it is for the defendant to present evidence that exonerates him from the "allegations" (Motive 7 of Directive 85/374) of the injurious event attributed to him.

A presumption of fact may be indicated as the main instrument used in this regard in case-law (Sośniak, 1970). It is justified by the capacious formula used in Article 231 of The Code of Civil Procedure (CCP), where it refers to "the possibility of drawing a conclusion". Undermining that presumption requires that the defendant proves the damage was not caused by the event attributable to him. In practice, this means having to show an actual other cause of the injury, i.e. proof to the contrary. The literature indicates that the success of such proof sometimes depends, to the detriment of the defendant, on the extent to which the opposite is shown to be the factor that must have (and not merely could have) caused the harmful effect (Janiszewska, 2004; Nesterowicz, 2001). A similar method of defense for the defendant is to show the impossibility of the cause of the harmful effect on the defendant.

In terms of proof, a distinction must be made between the increased probability associated with the occurrence of the cause under analysis, i.e., vaccination, and the probability with which one succeeds in demonstrating the existence of a regularity

covered by causation. These are not identical constructs (Nesterowicz, 2001). The former concerns the objectively existing risk of the harmful effect taking place when the examined cause (vaccination) occurs, the latter concerns the court's conviction whether or not such risk exists. It may transpire that the court will share a high or a low conviction of the 0.0001% increase in the probability of death as a result of vaccination.

Depending on this conviction, the causal link (i.e., an increase in the probability of death of one individual among a million vaccinated) will be considered proven or not, which in turn will either allow the claim to be accepted or dismissed. Generally speaking, the jurisprudence is satisfied - in terms of proof - with subsequently a very high probability (I ACa 192/00, 2000, II CKN 625/97, 1999), a high probability (I PR 174/67, 1967, II CKN 625/97, 1999, V CK 182/05, 2005, I ACa 107/97, 1997, I ACa 514/00, 2000, Nesterowicz, 2001, p. 1-6), a sufficient probability (II CR 671/76, 1977, Krupa-Lipińska, 2012, p. 91, Bagińska, Krupa-Lipińska, 2011, p. 246, Romańska, 2016, p. 104) or a substantial (V CKN 34/00, 2000, I ACr 374/92, 1992) degree of probability (II CR 692/73, 1973).[8] However, the suggestion implemented in practice, not to impose impossible evidentiary requirements on the aggrieved party, contradicts the general requirement of proving (Janiszewska, 2004, p. 119) the prerequisites of liability. In other types of "non-medical" lawsuits, without such facilitations, the claim would be dismissed.

A similar stance - sympathetic to plaintiffs - is presented by the Court of Justice of the European Union (CJEU). In its landmark ruling (C-621/15, 2017) on this issue, based on Article 4 of Directive 85/374/EEC on liability for defective products, the CJEU explained how to understand the requirement for the aggrieved party to prove the damage, the product defect and the causal link. Although EU member states have procedural autonomy (C-621/15, 2017), which includes, among other things, the assessment of evidence and the use of "non-scientific" presumptions (i.e., not involving strictly medical assessments), this must not lead to the requirements of the directive being overturned. At the same time, they were interpreted quite the opposite way as it would result from the linguistic interpretation. It was considered that the plaintiff had only to prove the basis of the presumption (C-621/15, 2017). Requiring certain proof of defect and a causal link would violate the directive by preventing an equitable sharing of risk.

On the other hand – and presumably in order not to create a complete illusion of the evidentiary requirements in Article 4 of the directive - it was pointed out that presumptions of fact could not be limited to irrelevant or insufficient evidence. Its automatic application, requiring rebuttal by the defendant before he can present his arguments (C-621/15, 2017), or approval of fixed and practically irrebuttable (C-621/15, 2017) factual presumptions, is no more possible either.

[8]*The probability of 50% was deemed insufficient.*

All of the above factors have blurry contours, justifying decisions based on judicial discretion. In fact, they prevent the verification of judicial decisions in doubtful cases. The positive value of the CJEU's statement focuses on the requirement to present, in the absence of other data, a significant number of cases relating to the disease in question "following" the event deemed as harmful (C-621/15, 2017). The aim is to distinguish situations in which there is such an actual consequence can be traced from cases of merely a temporal consequence, where one event simply occurs later than another. Such a distinction is impossible without a conclusive opinion froam a medical expert, and obtaining such an opinion is very difficult. For example, the hepatitis B vaccine may indeed cause multiple sclerosis (MS) in a certain percentage population of patients, but this may be the result of some personal characteristic traits or of some other external factor unrelated to the vaccine itself, where the administration of the vaccine does not have a *conditio sine qua non (csqn)* connection to the development of MS. This may be the beginning for proving a causal relationship, but it will not be sufficient (II CSK 285/07, 2007, Krupa-Lipińska, 2012, p. 93) even if comparison to the rest of the population will show a statistical incrase in the number of cases and they will precede the development of the disease.

When assessing the evidence, which only points to a certain degree of possibility of a causal link, the Polish court must make an unambiguous decision - either accept the link as proven or not (C. 25/51, 1951), but it cannot weigh the awarded damages against the degree of probability of the proven causality.

The liability of the National Health Fund (NHF) can therefore be pursued if the plaintiff succeeds in convincing the court of the causal link between the vaccination and the deterioration of health. This task is facilitated by the widely used factual presumptions and similar evidentiary mechanisms.

The above considerations make the practical violation of the ‘equality of arms principle’ clear in the compensation process. Separately, another institution, and also decidedly beneficial for the aggrevied party, needs to be pointed out. The "backup" basis for the public authority's liability is Article 417^2 of the Civil Code. Should the plaintiff fail to meet the already discussed lenient evidentiary requirements, there remains the possibility of applying the provision, which provides for liability based on equity principle. In this case, judicial discretion has a clear normative basis, since the scope of liability is determined by equity, as assessed by the court in the particular case. However, it cannot go beyond the indemnification of personal injury and harm. An additional necessary prerequisite justifying the award of compensation is the occurrence of personal injury.

It should be stressed that on the grounds of Article 417^2 of the Civil Code, which constitutes the basis for liability of public authorities only[9], the jurisprudence sometimes waives the requirement of adequacy of causality (Banaszczyk, 2015, p. 1410). This means that in cases generally considered to be based on the principle of illegality, and if a switch to the application of the principle of equity applies, the causal link between the vaccination and the health deterioration can only bear the *csqn character* (Banaszczyk, 2015, p. 1157, IV CSK 453/07, 2008). It would therefore be superfluous to evaluate this connection with the help of the adequacy criterion, immanently linked with previously discussed and increased probability. Even so, the relaxed causal requirement would have to be demonstrated in the manner adopted by the The Code of Civil Procedure (CCP). Meanwhile, with respect to the first reported cases of remote injurious effects, it is the *csqn*-type relationship that raises the most doubts. Once the relationship is established, we would generally again deal with normal circumstances[10].

Within the responsibility of MRA (GSRA from February 8, 2021), references may be made to the comments made above on the responsibility of the State Treasury. This agency purchased vaccines for the purposes of strategic reserves, which were then made available by a decision of the Minister of Energy (i.e., now the Minister of State Assets) taken *ex officio* or at the request of the Minister of Health in accordance with Article 18(2) of the Strategic Reserves Act of 29.10.2010 (See also, Leśniak, 2020)[11]. MRA was therefore not a direct perpetrator of a potential tort, but only (potentially) provided a tool for it in the form of a vaccine.[12] In view of this, the only basis for MRA's[13] liability can be Articles 416 and 422 of the Civil Code. The second provision for the liability of an aider (just as for the liability of an instigator,

[9]*It would come into play as to the acts of the State Treasury and the NHF (National Health Fund) and MRA-GSRA (Material Reserves Agency, subsequently Governmental Strategic Reserves Agency) as state legal entities.*

[10]*This is why Z. Banaszczyk is right when he somewhat ignores the significance of the distinction between satisfying the csqn test and adequacy.*

[11]*The issuance of such a decision would allow the State Treasury to be held liable for compensation for aiding in the infliction of damage (Article 422 of the Civil Code) provided the decision is to be held invalid, which, however, is doubtful. Since Article 422 of the Civil Code requires intentional guilt for aiding, liability could not arise for reasons analogous to those already outlined above in the comments concerning liability for incitement.*

[12]*The ownership status of vaccines is debatable. In principle, they should be purchased by MRA and included in its assets, as it had legal personality – being an executive agency in accordance with Article 18 of the Public Finance Act of 27 August 2009. However, we cannot exclude the possibility that e.g. the acquisition was made as an indirect substitution for the State Treasury, to which the vaccines are then transferred, or that such an effect is given by the decision on the release of strategic reserves, although prima facie, from Article 18.4.1 and 18.4.3 of the Act of 29.10.2010 on strategic reserves it rather appeared that the release did not result in the transfer of ownership of the reserves from MRA to State Treasury.*

[13]*More specifically, for the Governmental Strategic Reserves Agency, according to Article 67 pt. 4 of the Strategic Reserves Act.*

previously discussed) requires intentional guilt (Banaszczyk, 2015, p. 1424, Kondek, 2017, p. 597), which *in casu* does not occur. MRA's liability for defective vaccines under the regime of liability for a dangerous product (art. 449^1 et seq. of the Civil Code) will be further discussed in section 9.

The liability of the manufacturer of a defective vaccine is primarily a liability for a dangerous product. It is difficult to determine, however, and without knowledge of the ownership and registration structure of vaccine manufacturers, whether Directive 85/374 may be applied, since this instrument has had no relevance outside the European Union insofar as the conflict-of-law rule indicates the applicability of "non-EU" law. The same concerns the conflict-of-law rules, as outlined in Articles 4 and 5 of the Rome II Regulation *(Regulation (EC) No. 864/2007 of the European Parliament and of the Council of 11 July 2007 on the law applicable to non-contractual obligations).* It is difficult to conceive applying this Regulation before a court in a non-EU country, if the defendant manufacturer were to be domiciled there. The court must adhere to the conflict-of-law rules applicable only within its proper jurisdiction. However, if Polish law was deemed applicable, the plaintiff's situation would be quite advantageous.

Separately, it should be noted that suing the manufacturer only makes sense if the plaintiff is subsequently able to enforce a judgment in favor of awarding damages in the broad sense. In the case of a manufacturer based outside the EU, the judgment should be sought primarily where the manufacturer is in possession of assets open to foreclosure. I do not believe that the procedural rules of states outside the EU permit absolute recognition of judgments issued by courts in EU member states. A public policy clause should be expected in each case (cf. Art. 1146 § 1 (7) CCP). The same applies to the potential deprivation of the possibility to defend oneself before a Polish court, should the plaintiff wish to exercise the jurisdiction provided for in Article 35 of the CCP, which would justify bringing the action before the court covering the area where the vaccination took place, i.e. Poland. The evidentiary conveniences discussed above - if applied in a particular case - could constitute grounds for attempting to use the mechanisms indicated in the two preceding sentences to prevent recognition of a judgment rendered by a court of an EU Member State.

A view that there are likely to be clauses in EU vaccine supply contracts that exclude manufacturers' liability (Ojczyk, 2020) has been expressed in the media. Liability for a dangerous product cannot of course, be excluded within the EU (In contrast: Uchańska, 2020). On the other hand, it is permissible to conclude a contract corresponding to the model presented in Article 392 of the Civil Code, which, if the debtor is the State Treasury, will guarantee the manufacturer a longer process of securing the same result. Because the indemnity debts discussed here generally take

the pecuniary form (Kaliński, 2014, p. 452)[14], it is possible to imagine a situation in which, while seeking liability for a dangerous product, the manufacturer will refer the aggrieved party with its claims to the State Treasury, the NHF or GSRA. These entities - if they wish to voluntarily pay the manufacturer's debt - may do so, in accordance with Article 356 § 2 of the Civil Code. At the same time, they will thus execute an agreement to release the debtor from debt. However and for the reasons indicated in the preceding paragraph, if such voluntary settlement does not occur, then the aggrieved party may have great difficulty enforcing a potential judgment awarding payment from the manufacturer issued by a Polish court.

The claim of exemption from liability in the case of a conditional market release authorization is true only if it is understood in such a way that it exempts the manufacturer from liability for releasing the drug without an unconditional market authorization, which remains the rule (Uchańska, 2020). Beyond this understanding, it should be obvious that the manufacturer is normally responsable for product damage liability.

Let us now consider the liability of the treatment provider and the vaccination contractor. Since they are closely related organizationally, this justifies a combined discussion of this issue. Often, an additional link is included in the causal chain in the form of a referral by a physician to perform the vaccination. At other times, the physician himself conducts the referral and performs the vaccination. Because the search for liability makes sense first and foremost with regard to personal injury (which, as mentioned above, is of pecuniary nature), and this conceptual category is covered by special rules only within the scope of tort liability, further considerations are limited to this regime.

Obviously, this does not mean exclusion of the contractual liability of the medical entity for the actions of assistants or persons to whom the debtor entrusted the performance of the obligation, on the basis of Article 474 of the Civil Code[15]. If the patient accepts the reservation of service within the framework of the contract for service benefitng a third party (Article 393 § 1 of the Civil Code) (Morek, 2017, p. 328) linking the National Health Fund with the medical entity, then the latter becomes the patient's debtor with all the consequences characteristic for a classic contractual relation, including contractual liability under Article 471 of the Civil

[14]*I leave aside here the recognition of the compensation debt as Geldwertschuld, because it is not relevant to the course of the argument.*

[15]*I leave aside the issue of solidarity of provider's and the order recipient's liability to provide health care services, which is established by Article 27 (7) of the Act of 15.4.2011 on medical activity. It is extremely complicated. Doubts arise in particular as to whether the ordering party is liable for its own actions. If, on the other hand, it is acknowledged that we are dealing here with liability for someone else's act, the relationship of this provision with Articles 429, 430, 441 and 474 of the Civil Code would require analysis, in particular whether it does not constitute a superfluum (superfluity).*

Code (II CSK 517/15, 2016).[16] However, in the hypothetical cases analysed here, tort liability tends to be more favourable towards the aggrieved party, e.g. with respect to the statute of limitations (Banaszczyk, 2020, p. 1199), an opportunity to obtain disability benefits or receiving other benefits for those indirectly aggrieved individuals.

The case law does not approve of the liability of the medical entity for the actions of a doctor within the limits resulting from the article 429 of the Civil Code. It assumes that a doctor acts as subordinate and applies art. 430 of the Civil Code. This position raises far-reaching reservations, especially with regards to specialized treatment activities included in medical advice or referrals. Here, a doctor is not a subordinate of the medical entity (Wanatowska, 1968, p. 182, Bendza, 2016, p. 27). I am not convinced by the prevailing view that a doctor is subject to the authority of such entity (apart from organizational issues) (Nestorowicz, 2007, p. 5-7). Available references note that the concept criticized here has its source in "social considerations" of the People's Republic of Poland, and not in dogmatic arguments (Bendza, 2016, p. 28).

For this reason alone, this concept should be verified in connection with the change of the political system, but it never took place after 1989. It should also be noted here that even the representatives of the trend that looks at all medical activity as the relation between a superior and a subordinate, limit this qualification to employment relationships. Individual contracts for mandate *("umowa zlecenie")* or contracts for specific tasks *("umowa o dzieło")* do not create subordination (Nesterowicz, 2001, p. 9).

I admit that the position of the judicature remains quite defined regarding the application of article 430 of the Civil Code in the case of liability for medical treatment performed by physicians (Bendza, 2016, p. 28, II CSK 517/15, 2016, Nesterowicz, 2017, p. 127, see also: IV CSK 308/10, 2011, II CR 2/65, 1965, I ACa 277/14, 2015, I ACa 852/12, 2013, I ACa 2449/15, 2017, I ACa 1112/15, 2016, I ACa 403/19, 2019, I ACa 342/13, 2013, . I ACa 571/09, 2010, I ACa 624/13, 2013, I ACa 531/14, 2013, I ACa 511/14, 2014, I ACa 227/15, 2015. See also the more extensive arguments of Robaczyński, 2021, p. 271). It is a direction clearly contradictory to the one adopted on the grounds of article 145 of the Civil Code. It is opposed by the justification of the difference between art. 429 and 430 of the Civil Code: the relationship of authority, the essence of which lies in the superior's ability to issue orders binding upon the subordinate. This relationship does not exist in the case of Article 429 of the Civil Code, and therefore under this provision the

[16]*Therefore, I do not share the view expressed in the thesis of the judgment of the Supreme Court of 20 May 2016, II CSK 517/15, that the doctor was not bound by a contractual relationship with the patient in relations of this kind. However, the case is not obvious, because the view expressed in the thesis does not appear in the reasoning of the judgment and perhaps comes only from the publisher.*

responsibility of the person entrusting the task is lighter than that of the superior (Bendza, 2016, p. 29).

The responsibility for the acts of the dependent personnel performing vaccinations in the analyzed situation, lies with the medical institution as one which employs the staff. The foundation here is Article 430 of the Civil Code, which makes the medical entity absolutely liable for the faults of its subordinates. Employed staff can generally be considered subordinate to the medical entity. Its members are generally not liable to the patient, if they are employees - due to the regulation of Article 120 of the Labour Code. We therefore, come to the conclusion that, in practical terms, the responsibility of the medical entity while considering the varied degree of independence in duties performed by either world-class professors or ward nurses, does not differ at all from one another.

However, can guilt be attributed to these individuals? Since culpability is assessed according to the state of affairs at the time of the offence, this is unlikely to be the case. The vaccinator does not have - nor can he/she have – the knowledge of the unlawfulness of his/her actions, which is linked to knowledge of the vaccine's defectiveness. A different view would be acceptable only on the condition of accepting a concept of guilt that detaches culpability from illegality in the sense that it makes the awareness of illegality irrelevant to guilt. In Polish criminal law, however, as far as placement of the awareness of unlawfulness is concerned, in connection with the content of Article 30 of the Criminal Code (CC), the theory of guilt is adopted. Unlike the theory of intent, it holds that awareness of unlawfulness is an element of guilt, and not merely a component of the element of intentionality.

For any criminal act - not just an intentional one - is not a crime if the perpetrator was justifiably unaware of the unlawfulness. The theory of intent, on the other hand, limits the issue of such awareness to intentionality, i.e. the realization of the elements of the type of a prohibited act. (Żółtek, 2017, p. 485). As I believe, the scientific achievements of criminal law may be successfully adopted also in civil responsibility, especially taking into account the same understanding of guilt according to the normative theory. It means exclusion of the accusation of guilt against the medical personnel *in toto*, and therefore impossibility of assigning responsibility to the superior,[17] i.e. the medical entity.

As for the liability of the importer, i.e., MRA (subsequently Governmental Strategic Reserves Agency), apart from the already discussed aiding, also the liability for a dangerous product needs consideration. In this case, liability is more severe for MRA (GSRA), because it may exempt itself only by proving the exonerating circumstances listed enumeratively in Article 449^3 of the Civil Code and not by proving the lack of intentional fault, as in the case of aiding. First among those

[17]*Assuming of course, that Article 430 of the Civil Code should be applied here, which raises doubts.*

cirumstances is the so-called risk of development, regulated in Article 449^3 § 2 sentence 2 of the Civil Code.

The importer is not held liable if the dangerous properties of the product could not have been foreseen, taking into account the state of science and technology at the time of market release. The inability to foresee the dangerous properties of a product is assessed according to the state of science and technology at the time when the product was placed on the market. There is certainly no knowledge of these properties in the course of the current vaccination scheme. It will remain a matter of judicial interpretation, however, to what extent an attempt to exonerate for this reason can be overpowered by a hypothetical accusation of too narrow and hastily conducted clinical trials. In other words, to what extent can the risk of development be invoked when the state of knowledge at the time of the initiation and conduct of the vaccination campaign did not justify any anticipation of potentially dangerous properties of the vaccine, as this was the result of insufficiently in-depth studies.

The linguistic interpretation of the quoted provision indicates the impermissibility of differentiating assessments according to the state of knowledge acquired in a shorter or longer period of more or less extensive research (Uchańska, 2020). However, it is impossible to exclude such an understanding of the risk of development by the CJEU, which would consider permissible exoneration only within the scope of knowledge achieved as a result of maintaining standards of due professional diligence, i.e. in essence the highest level of due care. Such interpretation may be supported by the consideration for the protection of the aggrieved party.

However, one more point must still be made. The importer's liability covers the introduction of the product, i.e. the vaccine onto a "domestic" market (Article 449^5 § 2 sentence 2 of the Civil Code), only as part of one's own business activity. It is for this reason that MRA's (GSRA's) liability for importing vaccines as dangerous products will not come into consideration.

The vaccines were purchased by MRA under the agreements with the European Union. MRA (subsequently GSRA) in turn purchased the vaccines from the manufacturers (*Questions…,* 2020, Kawczyńska, 2016, p. 242). This chain of distribution allows for tort liability of the European Union itself to be considered as well and under Article 340(2) *Treaty on the Functioning of the European Union* (TFEU) (Kawczyńska, 2016, p. 242, 266, 291). Only the CJEU has jurisdiction in these matters, pursuant to Article 268 TFEU. The EU's involvement in the distribution chain is structurally analogous to that considered above in section 9. However, since Article 340 (2) TFEU refers to general rules, it is not admissable, in my opinion, to apply Directive 85/374 on liability for dangerous products or the national law that implements it - as they constitute a special regime. Do the general principles of tort liability support imposing it on the EU? If at the end of the comments in section 8 above, the theory of guilt was approved, then the lack of

awareness of the unlawfulness will be regarded as an obstacle to the imputation of guilt and thus to EU liability for the vaccine purchase as a form of aiding.

An easier way to justify liability would be to base it on the concept of lawful harm. Since it is not required for the injurious conduct to be unlawful in order to give rise to liability, it will in fact be crucial to show a causal link. The purchase of vaccines for onward distribution to Member States - in the event that they are subsequently found to be capable of causing a deterioration of one's health or inflicting bodily harm - certainly increases the likelihood of damaging the health of those vaccinated.

According to the CJEU (C-237/98, 2000, Kawczyńska, 2016, p. 295), the EU's liability for lawful conduct is permissible if the harm is real, unusual and specific, and a causal link between the EU's conduct and the damage is demonstrated. These conditions should not be very difficult to satisfy if the vaccines were scientifically proven to be defective, as has already been mentioned. Nor can the EU's liability in this case be precluded *a priori* by the statute of limitations, since under the first sentence of Article 46(1) of the Statute of the CJEU the limitation period is "five years from the event giving rise to that liability". This concept, however, is understood differently than the term "event giving rise to the damage" used in Article 442^1 § 1 of the Civil Code because the CJEU applies an interpretation that includes a harmful consequence (Kawczyńska, 2016, p. 158).

With regard to the EU's liability in connection with the administrative act of authorising the market release of a vaccine, it is necessary to outline the procedure for such authorisation in conditional terms, as applied in the case of the Covid-19 vaccines. The applicant submits an application for marketing authorisation to the European Medicines Agency (EMA). It evaluates the safety, efficacy and quality of the vaccine. If the EAL's recommendation is positive, the European Commission may authorise it for market release. Conditional approval is possible in emergency situations only. It is important to emphasize that under the EAL, the Committee for Medicinal Products for Human Use (CHMP), making a positive recommendation, must assume, on the basis of the evidence gathered, that the expected benefits of vaccination outweigh any risks associated with vaccination and not as much the premise that the vaccine is safe in the sense of excluding any harmful effects. Moreover, conditional approval requires the consent of a qualified majority of member states, which entangles them in the cause-and-effect chain amidst the approval process, independently of the involvement of the EU as such.

Material published by the EU (*Questions…,* 2020), assumes that conditional market authorization "guarantees ... safe use, efficacy and quality of the vaccine" and that the benefits outweigh the risks. Market authorization - as an administrative act - can therefore become the basis for EU liability for legal damages under the principles discussed above for liability covering vaccine purchases. There is a concurrence of causes attributable to the EU, one of which is at least partly of a dominant nature (the purchase of the vaccines) and the other - conditional authorisation - falls within

the purview of administrative acts, which undoubtedly fall within the category of *imperium*. Market release authorization does not have to be unlawful in this case, since the EU guarantees the safety of the vaccine. The imposition of special liability for harm caused legally is supported not only by the fulfillment of the requirements addressed by the above-cited CJEU case law,[18] but also, in particular, by the "guarantee of safety" mentioned. In my opinion, it allows for the use of constructions adopted by the Polish civil law science on the grounds of Article 391 of the Civil Code to assess the extent of the damage.

It should be pointed out that, with regards to Covid-19 vaccines, and contrary to the opinions expressed in the daily press, there is no obligation to abolish the liability of the manufacturer in connection with the emergency market release authorisation mentioned in Article 5(2) of Directive 2001/83, which is issued by a Member State in respect of a medicinal product that is not covered by the authorisation. Market release authorisation by the European Commission excludes that special mechanism. In other words, either there is a conditional or unconditional market authorisation from the European Commission or otherwise an EU Member State issues an emergency distribution authorization.

Summarizing the issue of liability for damages for vaccines, it is necessary to emphasize its differentiation depending on the factual basis of the action of the potential debtor, participating - *sensu lato* - in the vaccination. The liability of the State Treasury for the promoting of vaccinations qualified as inducement to a tortious act needs to be ruled out. The same applies to MRA's (GSRA's) liability for the purchase of vaccines as aiding in a tortious act. Neither is the MRA (GSRA) liable under the tortious subregime for a product as an importer.

Similarly, the National Health Fund is not liable towards the patient under the contractual regime, but its liability in tort is possible. It is to be expected that under liability in equity the justification for its imposition will be easier, as it does not require fault nor unlawfulness, and neither an adequate causal link, at least according to the more liberal standpoint. However, even stopping at the necessity of a *csqn*-type relationship implies the need to convince the court of the existence of such a relationship, which can be very difficult with respect to the first instances of an injurious effect. This is combined with the reluctance of expert witnesses to qualify very rare health damages as vaccine consequences.

The manufacturer's liability for vaccines as a dangerous product must also be allowed to arise. The success of an action in this case will depend, in addition to the causation issues, on the conflict-of-law rule indicating the EU Member State's law as applicable. It is also not possible to contractually exempt a product from product liability, especially with respect to the patient as a third party. Similarly, there is no

[18] *Indicated in the last paragraph of the previous section.*

general exclusion of producer's liability on the basis of a conditional market release authorisation.

As far as the liability of the medical entity for dependent or independent medical personnel is concerned, it would in practice potentially come into consideration on the basis of Article 430 of the Civil Code. Since its prerequisite is the fault of the subordinate, this liability will not arise. The subordinate is not aware that the vaccination is unlawful.

On the other hand, the European Union's liability "on general principles", provided for in the TFEU and based on the aiding of bodily harm or health damages by means of supplying an instrument in the form of a vaccine, cannot arise due to the lack of the necessary inclusion of unlawfulness in the willful guilt required here (similarly to the aforementioned liability of the State Treasury). The EU's liability as an importer under the product liability regime is also subject to be ruled out. On the other hand - also with regard to the purchase and distribution of vaccines to Member States' agencies - it seems possible to accept its liability for damage caused legally, according to the construction adopted by the CJEU (especially in view of the specific nature of the damage). In addition, the EU will be liable in damages, also for "lawful" harm - for the administrative act of authorizing the vaccine on the market, since by that act it guarantees the safety of its use. Of course, the caveat regarding the proof of causation presented three paragraphs above, will apply here.

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