

ASSESSING LEGAL RESPONSIBILITY IN ROMANIAN PHARMACEUTICAL PRACTICE

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Abstract

By law, doctors and pharmacists may be held liable for professional misconduct. The pharmacist's roles and responsibilities have been expanding in patient care, particularly in times of COVID-19 pandemic and now they may perform a diverse range of professional activities as attested by the newly adopted legislation, Minister of Health's Order no. 2382/2021. However, pharmacist malpractice is different than medical malpractice because pharmacists' responsibility is based on pharmacist professional standards and legal duties. Despite the existence of overlaps, there are differences between the doctors' and the pharmacists' professional duties. Our study identified ten main legal professional duties of pharmacists and provided examples of negligence. The results could be used as a tool for malpractice risk assessment and management. We also argue that the Romanian legal framework allows malpractice claims to be filed by both the patient and/or the doctors when shared accountability is involved and this increases the pharmacists' risk of being sued. Moreover, the chief pharmacist is responsible for the pharmacy's overall activity, including liability for tasks entrusted to subordinated personnel.

Rezumat

În conformitate cu legea, medicii și farmaciștii pot fi răspunzători pentru comportament profesional necorespunzător. Rolurile și responsabilitățile farmaciștilor s-au extins, în special în perioada pandemiei COVID-19, aceștia putând să desfășoare, în prezent, activități profesionale diversificate, așa cum rezultă din legislația adoptată recent, Ordinul Ministerului Sănătății nr. 2382/2021. Cu toate acestea, malpraxisul farmaceutic este diferit de cel medical, pentru că răspunderea farmaciștilor este evaluată în funcție de standarde profesionale și responsabilități legale specifice farmaciștilor. Deși există suprapuneri, responsabilitățile profesionale ale medicilor și farmaciștilor sunt, în general, diferite. Studiul nostru a identificat zece responsabilități profesionale principale ale farmaciștilor și exemple de neîndeplinire a acestora. Am arătat, de asemenea, că acuzațiile de malpraxis pot fi inițiate atât de pacient, cât și de doctor atunci când responsabilitatea este divizată între acesta și farmacist, iar acest lucru crește riscul formulării acuzațiilor de malpraxis împotriva farmaciștilor. Nu în ultimul rând, farmacistul șef răspunde pentru întreaga activitate la nivelul farmaciei, incluzând și responsabilitatea pentru sarcinile delegate personalului subordonat.

Keywords: pharmacists, malpractice, legal responsibility, extended roles, extended liability, vulnerabilities, COVID-19, SARS-CoV-2

Introduction

In Romania, when patients suffer an adverse reaction or claim severe injury due to medicine administration it is uncommon to sue the pharmacy and/or the pharmacists. As such, malpractice litigations involving pharmacists have been rare.

Under Romanian legislation, the pharmacists' role exceeds a simple process of selling medicinal products or as some authors describe it “pill-counting or distribution” [6]. As it was shown in other jurisdictions: “This particular approach to pharmacy practice expands traditional pharmacist responsibilities of dispensing pharmaceuticals and providing drug information to optimizing patients' drug therapy outcomes” [37].

The pandemic context brought into discussion previous initiatives such as *telepharmacy* counselling [48], including virtual consultations [24], use of social media

for medico-pharmaceutical acts [26] and home delivery of medicines [12].

As a result of legislative changes due to the pandemic situation, Romanian pharmacists were given greater authority and extended responsibilities. Currently, in Romania, pharmacies are allowed to provide COVID-19 testing in their facilities and vaccine administration [35]. According to these legislative amendments, the following activities can be performed by pharmacists – *measurement of biological parameters, diagnose testing and vaccines' administration, under the conditions established by a Minister of Health's Order*. Moreover, according to the above-mentioned Order no. 2382/2021 [31], pharmacists' roles were seriously extended to include a series of medical acts such as management services for chronic patients, for example hypertensive or diabetic patients or monitoring a series of patients

such as those affected by lung diseases or those undergoing treatments with oral anticoagulants.

New roles imply new responsibilities [9] and our review [41] intends to identify legal implications of such extension of pharmacists' traditional roles, including possible vulnerabilities for pharmaceutical practice.

Research questions

What are the reasons why pharmacists' legal liability is not frequently questioned? Is it because the legal system does not allow it or due to insufficient knowledge of legal provisions and limited judicial practice in this field?

Which are the potential causes of malpractice legal actions arising out of pharmaceutical practice in Romania?

Does an increased role in COVID-19 pandemic trigger increased legal liability?

Are pharmacists at risk?

Objectives

By answering the above questions, the review intends to identify the legal regime [33] related to pharmacists' liability, pharmacists' standards of care and types of negligence.

Materials and Methods

Review of the Romanian legislation related to pharmacists' professional activities and of the relevant judicial practice (national and international) related to pharmaceutical professional misconduct (pharmacist malpractice).

Results and Discussion

The Romanian legal framework clearly and precisely defines the pharmacist's legal liability for professional misconduct (pharmacist malpractice).

Pharmacists' legal liability (pharmacist malpractice)

By law [17], the pharmacist is included into the category of *medical personnel*, which may be held responsible for his/her actions if some legal conditions are met. Moreover, the national law defines *malpractice* as the professional error committed when exercising a medical or a *medical-pharmaceutical act*—thus, resulting in civil liability. The law establishes, as a general principle, the pharmacist's professional liability if the two definitions (i.e.: *medical personnel* and *malpractice*) are read in conjunction. The Pharmacy Law no. 266/2008 includes a general provision [20] according to which violation of this law may lead to disciplinary, administrative and civil liability, as the case may be.

Four legal elements need to be proven in a malpractice lawsuit [44]: (i) duty of care, (ii) breach of duty, (iii) causation and (iv) prejudice. In malpractice claims, it has to be proven that the pharmacist had a legal obligation (e.g., to warn against side effects of a certain medicine), that obligation was breached, and damages

were suffered by the patient as a result of such breach [47].

First, duty of care and breach of duty are to be proved in medical malpractice judicial practice. Bolam test ("In malpractice there is a reasonable doctor standard. The law is not concerned with a best doctor standard or even a good doctor standard; all that is required is for a reasonably prudent doctor to apply ordinary skills") is used for setting the standard of practice [47]. According to this test, the specialist is obliged to perform the medical act at the standard of a specialist with basic professional competence and qualification (*ordinary skilled professional*). It is not mandatory for the professional to have the highest degree of knowledge and experience compared to which his/her performance is considered wrong or negligent [16].

The pharmacist's roles and responsibilities have been expanding in patient care (particularly in times of COVID-19 pandemic) and now they may perform a diverse range of professional activities. Pharmacist malpractice is different than medical malpractice because pharmacists' responsibility is based on pharmacist professional standards and legal duties [17]. Despite the existence of overlaps, there are differences between the doctors' and the pharmacists' professional duties. The pharmaceutical practice has faced an increase in civil litigation over the last twenty years. Some patients are asking the judiciary to hold pharmacists accountable for failing to use their position in the healthcare system to protect customers from drug-related injuries [25].

A study in the UK has found that one percent of dispensed prescriptions contain errors, of which 0.18 percent represent serious errors [4]. Another UK study on the incidence, nature, and cause of dispensing errors in community pharmacies estimated that, on average, for every 10,000 dispensed items there are approximately 22 near misses and 4 dispensing errors [39]. It has been estimated that, on average, a pharmacist will make a dispensing error every month [36]. Studies in the US found that the average prescription errors are about 3 to 5 percent, with about one percent of these being potentially serious errors.

Pharmacists' professional duties

In Romania, pharmacists' professional obligations and the standards of their professional conduct are developed/detailed in the law and in the curriculum of training for clinical pharmacy specialty which provides the objectives of the training [29].

A framework of different Romanian legislative acts was reviewed to identify the pharmacist's professional obligations in 2021. "The legislation includes a general law on health [15, 17], complemented by a law concerning the pharmacists' profession [19] and a number of secondary regulations defined by the Ministry of Health

through several Orders [46] or by the Regulatory Body (such as the Code of Conduct [40])” [49].

Based on the Romanian legislation, we identified 10 (ten) main professional duties (detailed in Table I).

Table I
The pharmacists’ main professional duties

1.	Counselling
2.	Generic substitution
3.	Telepharmacy counselling
4.	Medical prescription’s evaluation (pharmacotherapy, overdose, underdose, incompatibilities, interfering actions)
5.	Collaboration with the doctor in order to establish and follow-up the therapy
6.	Preparation, storage and administration of medicines
7.	Distribution, storage and supplying medication
8.	Drugs’ prescription without a physician’s intervention
9.	Screening and diagnostic services, including SARS-CoV-2 testing
10.	Vaccines’ administration, including SARS-CoV-2 vaccines

Negligence (breach of duty)

Negligence (breach of duty) could result in pharmacist malpractice litigations initiated by both the patient and/or the doctors when shared accountability is involved. We will further present examples of negligence for each identified duty [27].

Counselling patients

Duty. When providing advice on medicines [46] a pharmacist must respect a series of guidelines when informing patients [43], as detailed below: (i) the pharmacist must respect the patient’s voluntary decision and the patient must have access to other information useful for personal needs related to his/her health status; (ii) the information offered to the patient must be simple, easy to understand and presented according to the patient’s degree of understanding; (iii) when counselling patients regarding drugs’ use, the benefits and risks of using medicines must be presented in a balanced way; (iv) the pharmacist must convince patients of how important it is to read the information about the medicine they are going to take and to encourage them to ask all the useful questions about it; (v) the pharmacist must advise patients to keep a complete list of all medicines they use (prescribed or by self-medication), which they must make available to the attending physician, but also to the pharmacist; (vi) the pharmacist must inform the patient about how to store the medicines to ensure that their quality is maintained and that the safety of the patient and his/ her family is guaranteed; (vii) the pharmacist will provide all the necessary information for the safe, correct, and effective use of the medicine, in a form appropriate to the needs of each patient. In addition to oral communication, the pharmacist’s information or advice may also be in written form or by other appropriate means. Contraindications, drug interactions, possible side effects mentioned in the patient information leaflet should be repeated and emphasized before the drug is released; and (viii) when informing patients, the pharmacist must include the following mandatory elements: the drug’s action, the method of administration (how, when and how much), the duration of treatment,

possible side effects, interactions, and precautions to be followed by the patient.

Breach of duty. In this case a breach of duty may include: (i) providing wrong or incomplete information regarding drugs’ administration and possible side effects [14] and (ii) neglecting to advise patients of potential side effects or interactions with other drugs.

Generic substitution [13]

Duty. The legislation includes some requirements regarding drugs’ substitution which configure the pharmacist’s legal duty in this case. Thus: (i) new drugs should have the same qualitative and quantitative composition in active ingredients, the same pharmaceutical form, the same concentration, and their bioequivalence should be demonstrated by appropriate studies; (ii) the patient will be informed, and his/her consent is needed for substitution; and (iii) the pharmacist must take into consideration some criteria when deciding upon drugs’ substitution: (a) the patient’s consent; (b) the patient’s ability to understand and manage change; (c) the presence of inactive ingredients (e.g., lactose), which can limit the products’ choice; and (d) confusions that may be generated by different pharmaceutical form/ packaging [13].

Breach of duty. In case of generic substitution, breaches of duty may include: (i) lack of patient’s information/ consent, (ii) choosing a medicine without respecting the scientific guidelines in this respect. The provisions issued by the Romanian National Health Insurance House contract’s rules state that the pharmacist’s recommendation for trade names related to international non-proprietary name (INN) prescribed by the doctor should be made starting with the cheapest medicine within the respective INN [10]. In our opinion, it is problematic when the generic substitution decision is based solely on costs without taking into consideration all the other scientific requirements (allergies, side-effects, components) and therefore might be considered malpractice.

Telepharmacy counselling [8, 21]

As a result of the pandemic situation, the Romanian health legislation was amended [11] to include tele-medicine, which includes *telecounselling*.

We notice that pharmacists, like doctors, are encouraged to offer *telecounselling*, in the absence of some specific standards of practice. Therefore, to determine if a certain performance was negligent, the ordinary standard of practice (and which does not include *telepharmacy*) shall be used. In our opinion, this represents one major vulnerability for this specific type of medico-pharmaceutical acts.

The legislation is generic and needs to be further adjusted as a result of practice, given the specifics of medico-pharmaceutical acts at distance. In practice, it might be difficult for a pharmacist to respect all the pharmaceutical practice requirements when it comes to providing complete and correct at distance advice on medicines without any guidelines.

Medical prescription's evaluation

According to the Romanian legislation, the general rule is that prescribing drugs is dependent on a medical prescription, with some exceptions strictly regulated by law. From a legal perspective, the fact that all these rules are included in various acts is confusing and triggers uncertainty when trying to determine this profession's legal regime and the situations in which pharmacists may be held liable for their activities.

Duty. The pharmacist must: (i) identify the patient and the doctor who prescribed the drug; (ii) verify the medical prescription's authenticity; and (iii) identify the medicine, verify the pharmaceutical form, dosage, concentration, doses, presentation, way of administration and duration of treatment.

Breach of duty. In this field, examples of breaches of duty include [42]: (i) lack of verification of each step (pharmacotherapy, overdose, incompatibilities, under dose, interfering actions, wrong medication or dosage) or (ii) not warning the patient about the maximum dosage. The Law provides one way to mitigate risks related to an incomplete medical prescription's evaluation, stipulating that it is recommendable for each pharmacy to develop a database for each patient, mentioning the medications taken. These databases must be kept with the patient's prior and explicit consent [46].

Collaboration with the doctor for therapy set-up and follow-up

Duty. The pharmacist shall use all his/her professional experience to assess the medical prescription against: (i) all therapeutic aspects (pharmaceutical and pharmacological); (ii) its adjustment to the patient's status; and (iii) the drug's contraindications and interactions. Should any problem arise following the prescription's assessment, the pharmacist shall contact the prescribing doctor.

Breach of duty. In other jurisdictions [28], it was decided that the pharmacist had a legal duty to warn the doctor about a contraindication, and lack of such warning represents a breach of duty. We can argue that, under the Romanian law, Courts might decide

in a similar way given that the pharmacist has the obligation to contact the prescribing doctor for any identified problem.

Preparation, storage, and administration of medicines Duty. Preparation of medicines for administration is recognised as an area with a high risk of error [38] because it involves: (i) knowledge of ingredients, equipment, compatibility, stability, technique needed to compound sterile and non-sterile extemporaneous prescriptions; (ii) qualified personnel; (iii) protective apparel; (iv) specifically designated area; (v) appropriate equipment; (vi) packaging; and (vii) caution regarding expiration date.

Breach of duty. The most common mistakes [1] involve the impossibility to determine the prescribed drug's concentration, compounding, mixing and the labelling of drugs with incomplete medical indications. When a preparation includes more than three drugs, the risk of preparation error increases 1.8 times [7].

Distribution, storage and supplying medication

Distribution, storage and supplying of medication must follow a series of guidelines [32] regarding storage units, equipment, temperature's control, documentation attesting the drugs' origin and quality. Non-compliance of these rules might trigger pharmacies' legal liability. Examples of breach of duty include supplying false, contaminated, or expired medicines.

Drugs' prescription without a physician's intervention Duty. Several models for prescriptions issued by pharmacists have been implemented internationally [5]. We identified 4 (four) situations in which pharmacists are allowed to prescribe drugs without a physician's intervention in the Romanian legal and regulatory frame-work: (i) OTC prescribing; (ii) clinical pharmacist prescribing; (iii) dispensing medicines in specific circumstances; and (iv) emergency pharmaceutical services. In all these 4 (four) situations, the pharmacist shall bear full responsibility.

OTC prescribing. Pharmacists can recommend a series of medicines which can be dispensed without medical prescription in case of patients' symptoms (OTC medication) [46]. In case of OTC prescribing, the pharmacist should be sure to receive sufficient information to assess the patient's individual and specific health problems. The pharmacist will rely on his/her experience in selecting OTC medicines, depending on their quality and safety. When dispensing an OTC medicine, the pharmacist must make every effort to ensure that the patient has information about: (a) the drug's action; (b) mode of administration (how and how much); (c) duration of treatment; and (d) side effects, contraindications, and possible interactions with other drugs in the patient's treatment. Innovations in this area allowed some medicines to be reclassified from "prescription only" to "pharmacy" availability [34].

Clinical pharmacist prescribing. The clinical pharmacist must be able: (a) to make decisions in the process of choosing the effective, safe and appropriate drug

from the benefit – cost ratio point of view of the analysis; (b) to provide information to patients and healthcare professionals regarding the scientific and rational use of medicines; and (c) to monitor the patient's drug therapy [46].

Dispensing medicines in specific circumstances. The Romanian Code of pharmaceutical deontology includes some specific situations when the pharmacist may prescribe drugs [5] without a medical prescription: (i) the patient is chronically ill, and he/she is known by the pharmacist or is registered in the pharmacy's records as user of the requested drug, but for various reasons could not reach the doctor; (ii) the patient does not have a prescription, but presents a hospital discharge summary/note, a medical letter, etc.; (iii) the patient presents a prescription whose validity has expired; (iv) the patient presents a scheme of treatment initiated by the prescribing physician; (v) the patient is in transit and cannot continue treatment; and (vi) other emergency situations in which the pharmacist will decide to prescribe a medicine for a limited duration, or until a medical prescription is obtained, recommending the patient to set up an appointment with the family physician, the health centre or the emergency unit, or advising the patient to call the emergency number, as applicable.

Pharmacies in the rural area may provide emergency pharmaceutical services also when there are no medical offices in that area or the doctor is not present. In case of independent prescribing, the pharmacist bears full responsibility for patient's assessment and diagnosis. This is the reason why the Code of Conduct includes some very specific conditions in which the pharmacist can prescribe drugs without the doctor's intervention. Moreover, according to pharmacies' law, the sale and release of medicines allowed without a medical prescription is permitted only for community pharmacies and drugstores authorized under this law, with prior notification of the Ministry of Health of their intention to develop this activity, under the conditions established by an Order of the Minister of Health.

Emergency pharmaceutical services. According to the Romanian Law, a pharmacist can provide emergency pharmaceutical services [23] under some conditions: (i) the pharmacist must ask the patient or his/her attendant all information related to the urgency of his/her request, namely the current medication, the existence of other conditions or allergies, as well as other aspects that may influence the pharmacist's decision; (ii) the doses delivered may be for maximum 24 hours, on working days, and for maximum 72 hours, for weekends and legal holidays, and any such intervention will be accompanied by the pharmacist's recommendation that the patient should consult the doctor immediately; (iii) in case of children, the release of a drug will be accompanied by the recommendation for parents to consult the family physician as soon as possible or to call the emergency service; (iv) psychotropic and

narcotic drugs are not subject to emergency pharmaceutical services; (v) the pharmacist's decision will be made considering the medical situation for which the drug is requested, the therapeutic group to which the drug belongs, the drug's side effects and contraindications; and (vi) to be able to provide emergency pharmaceutical services in proper conditions, the pharmacist is obliged to ensure first aid, within the limits of his/her competence and to request the intervention of specialized services, informing on the measures taken at his/her own initiative.

Breach of duty. In this case, breaches of duty include (i) exceeding the limits in which emergency pharmaceutical acts may be performed; (ii) prescribing drugs without a medical prescription in other situations than the ones provided by law; and (iii) prescribing wrong medication e.g., improperly prescribing contraindicated drugs or drugs that are known to have adverse side effects for the patient's medical conditions and/or adverse interactions with other prescribed medications [47].

Screening and diagnostic services, including SARS-CoV-2 testing

In the pandemic context, the Romanian legislation was amended [3, 30] to include pharmacists' possibility to perform COVID-19 testing. Pharmacies that want to perform such medical activities need to obtain a special notice and one of the conditions for obtaining it is conducting a specific training course for the personnel involved in the testing activity.

To perform this medical procedure, the patient's informed consent must be obtained [18]. It must be noted that, in this case, the pharmacist bears full responsibility for this medical act and he/she will be held responsible in case of an error or for performing the COVID-19 testing without patient's informed consent. Given the specifics of this medical act, special attention must be given to the specific training course mentioned above [45].

Vaccines' administration, including SARS-CoV-2 vaccines
In Romania, vaccination in pharmacies is regulated by Pharmacy Law no. 266/2008 as recently amended and republished [35]. However, in practice, this is not yet possible due to the lack of implementing regulations [41]. As a result of the pandemic situation, the legislation was changed to allow pharmacists to administer vaccines, including SARS-CoV-2 vaccines [35]. These legal provisions are not currently used in practice. However, it should be noted that this is a serious medical act for which pharmacists should be thoroughly prepared. In case of an error in performing such medical act, the pharmacist will bear full responsibility. Moreover, to perform such an act, the patient's informed consent must be obtained.

Sharing legal responsibility with doctors

We notice that some of the acts/performances are undertaken alone by the pharmacist with no intervention

of a prescribing doctor. In this case, the pharmacist will bear full responsibility for his/her acts. For procedures where a prescribing doctor is also involved, it is possible to share the responsibility and legal liability between the two [22].

Shared responsibility is possible under Romanian law because the legislation includes a general principle

according to which all people involved in the medical act will be held liable proportional with their degree of guilt [17].

The relationship between the breach of duty and type of legal liability (full or shared with the prescribing doctor) is presented in Table II.

Table II

Pharmacists' type of accountability (full or shared with the prescribing doctor) in different malpractice situations

	Area of vulnerability (Breach of duty) - Examples	Types of accountabilities (full or shared with the prescribing doctor)
1.	Providing wrong information regarding drugs' administration and side effects	Shared /Full
2.	Generic substitution without respecting all the scientific guidelines in this respect	Full
3.	Providing wrong information regarding drugs' administration and side effects in telepharmacy counselling	Shared/Full
4.	Not warning the patient about the maximum dosage	Shared
5.	Not warning the physician about a contraindication	Shared
6.	Errors in preparation, storage and administration of medicines	Full
7.	Supplying medication of poor quality (contamination, using expired medications)	Full
8.	Errors in exercising prescribing rights without a physician's intervention	Full
9.	Errors in screening and diagnostic services (including SARS-CoV-2 testing) and/or lack of patient's informed consent	Full
10.	Errors in vaccines' administration (including SARS-CoV-2 vaccines) and/or lack of patient's informed consent	Full

Pharmacist's legal responsibility for subordinated personnel

The legislation includes some specific rules regarding the chief pharmacist's legal responsibility. Thus, the chief pharmacist is responsible for the overall pharmacy's activity. He/she must coordinate, verify, and evaluate each task entrusted to subordinated personnel. Moreover, all pharmaceutical aspects related to the pharmacy's supply are the responsibility of the chief pharmacist [46]. Therefore, even if in practice some tasks are entrusted to other people, the chief pharmacist will be responsible for the pharmacy's activity.

In a recent Romanian malpractice case, one patient received a prescription in a wrong dosage, approximately seven times higher than normal. With that prescription, the patient went to a pharmacy, and, although the dosage on the prescription was toxic, the pharmacist ordered the required number of drugs (the pharmacy was out of stock) and simply gave them to the patient. It is not clear why the pharmacist's liability was not questioned in this particular case, but, based on our study, it can be argued that the pharmacist's liability could have been questioned. Moreover, in our opinion, this represents a typical example of possible shared accountability between doctor and pharmacist.

Consequently, a malpractice claim could have been filed by both the patient and the doctor (to share the responsibility/burden of compensation payments). Most probably, the pharmacist's legal liability was not questioned, because the Romanian medical legislation is young. In 2006, the legal medical malpractice definition and medical personnel's legal liability for

medical errors were established and, therefore, the medical and pharmaceutical malpractice jurisprudence is limited. However, we have noticed an exponential increase of malpractice allegations involving doctors since 2006.

Breach of professional duty in the pharmaceutical practice [48] could result in malpractice litigation and this risk increases with the expansion of both the pharmacist's role and competence (particularly in times of COVID-19 pandemic). The claims could be filed by both the patient and/or the doctors when shared accountability is involved. Romanian pharmacists can be held legally liable for negligence in performing their professional duties. Sentencing pharmacists to paying compensations to patients is not possible unless a Court of Law identifies the pharmacist's duty, his/her negligence (breach of duty) and the causation link with the patient's injury. The chief pharmacist is responsible for the overall pharmacy's activity, including liability for tasks entrusted to subordinated personnel.

Conclusions

We conclude that the extension of the pharmacist's role influences the professional responsibility, and, in case of shared accountability (together with the prescribing doctor), the pharmacist's vulnerability doubles, because malpractice litigation could be initiated by both the patient and the physician. In our review, we identified 10 (ten) main professional duties and revealed examples of negligence (pharmacist malpractice). In this way, we provide pharmacists with a tool for malpractice risk assessment and management.

The stage for malpractice litigations involving pharmacists is set by the Romanian lawmakers and a higher incidence of malpractice litigations in this field is to be expected – it's only a matter of time.

Conflict of interest

The authors declare no conflict of interest.

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