

Paweł Kowalski

SWPS University, Poland

e-mail: pkowalski@swps.edu.pl

ORCID:0000-0003-2078-7712

INFORMED CONSENT TO ALGORITHMIC DIAGNOSIS IN MEDICINE UNDER SCHUFA AND ARTICLE 22 GDPR

Abstract

The CJEU judgment in SCHUFA (C-634/21) redefines the ‘decision’ of Article 22 GDPR: if a score generated by one entity effectively determines another entity’s decision, the data subject is entitled to the protections of Article 22, regardless of whether a human formally signs off. This article asks what that reasoning means for medicine: when an algorithm’s output shapes a physician’s clinical judgment, does the patient have a right to know, and what must they be told? The discussion confronts the SCHUFA doctrine with informed consent requirements under Polish law and the new Article 12 of the Code of Medical Ethics, situates it against the international debate, distinguishes diagnostic from cognitive uses of AI through operational criteria, examines liability for algorithmic harm after Directive (EU) 2024/2853, and addresses the problem of large language models – tools physicians already use but which cannot be meaningfully certified.

KEYWORDS

artificial intelligence, automated decision-making, GDPR, informed consent, patient autonomy, AI Act, Code of Medical Ethics, large language models, medical liability

SŁOWA KLUCZOWE

sztuczna inteligencja, zautomatyzowane podejmowanie decyzji, RODO, świadoma zgoda, autonomia pacjenta, ustawa o sztucznej inteligencji, Kodeks Etyki Lekarskiej, duże modele językowe, odpowiedzialność medyczna

I. INTRODUCTION

Artificial intelligence is entering clinical practice faster than the law can keep up. Diagnostic algorithms now assist – and sometimes effectively determine – medical decisions, yet the legal framework for patient rights was built for an era of purely human judgment. The CJEU ruling of 7 December 2023 in SCHUFA (C-634/21)¹ marks a shift in how courts read the GDPR's automated decision-making provisions, with implications well beyond credit scoring.

The patient's right to information underpins modern medical law as the precondition for valid consent and patient autonomy; without it, the patient cannot make an informed choice.² Fulfilling the statutory duty to inform gives the patient a real share in the therapeutic process and a conscious part in choosing the method of treatment.³

AI inserts a third actor into what was once a dyadic relationship. The algorithm – opaque, probabilistic, and in some sense autonomous – now sits between physician and patient.⁴ Can the doctrine of informed consent, developed for human medicine, work when algorithms do the diagnosing?

That question is contested internationally. In the American debate, I Glenn Cohen has shown that the common law of informed consent, as it stands, would, in general, not require disclosure of the physician's reliance on AI, save for a few narrow fact patterns.⁵ In the bioethics literature, Joshua Hatherley attacks the 'disclosure thesis' head-on, arguing that none of the standard arguments for a duty to disclose

¹ Case C-634/21 *OQ v Land Hessen*, joined party: SCHUFA Holding AG [2023] ECLI:EU:C:2023:957 (SCHUFA).

² Dorota Karkowska, comments 1 and 2.2 to Art 9 in Karkowska (ed), *Prawa pacjenta i Rzecznik Praw Pacjenta. Komentarz*, LEX/el. (Warszawa 2021).

³ Karkowska, comments 1 and 4 to art 9 in Karkowska (n 2).

⁴ Mirosława Malczewska, comment 1 to Art 31 in Eleonora Zielińska (ed), *Ustawa o zawodach lekarza i lekarza dentystry. Komentarz*, LEX/el. (Warszawa 2022).

⁵ I Glenn Cohen, 'Informed Consent and Medical Artificial Intelligence: What to Tell the Patient?' (2020) 108 *Georgetown Law Journal* 1425.

machine learning use survives scrutiny.⁶ Ploug and his co-authors, by contrast, complain that the EU's risk-based regulatory architecture protects patients only in the aggregate and, as they put it, 'fundamentally disempowers' the individual patient.⁷ Against that background, the Polish solution – a binding deontological norm conditioning the use of AI on the patient's informed consent – is anything but obvious.

This article reads SCHUFA through the lens of medical law. If the Court's functional approach applies in healthcare, AI-assisted diagnoses may trigger Article 22 even where a physician retains nominal authority. A separate section examines Article 12 of the Code of Medical Ethics – the first Polish deontological norm on physicians' use of AI. Both point in the same direction: patients are entitled to know when algorithms play a role in their care. The closing sections turn to liability and to proposals *de lege ferenda*.

II. FACTS OF THE CASE AND THE RULING OF THE COURT

The case concerned a German credit information bureau which generated, by automated processing, credit scoring – a probability value for the borrower's future behaviour – and transmitted it to financial institutions, which made lending decisions on its basis. The applicant, who had been refused credit due to an unfavourable score, challenged this practice under Article 22 GDPR.⁸

The preliminary question was whether a score calculated by one entity is a 'decision' under Article 22(1) GDPR when another entity relies heavily on it.⁹ Advocate General Pikamäe advocated a broad interpretation, covering also third-party processing results that decisively influence the final outcome.¹⁰

In its judgment, the Court adopted a functional understanding of a decision based solely on automated processing: the automated establishment by a credit information agency of a probability value concerning a person's ability to service a loan

⁶ Joshua Hatherley, 'Are clinicians ethically obligated to disclose their use of medical machine learning systems to patients?' (2025) 51 *Journal of Medical Ethics* 567.

⁷ Thomas Ploug and others, 'The need for patient rights in AI-driven healthcare – risk-based regulation is not enough' (2025) *Journal of the Royal Society of Medicine* (online first) 2–3, doi 10.1177/01410768251344707.

⁸ SCHUFA (n 1), paras 14–16.

⁹ SCHUFA (n 1), paras 27 and 40.

¹⁰ Opinion of AG Pikamäe in SCHUFA, ECLI:EU:C:2023:220, points 38 and 48, referred to in the judgment (n 1), paras 46 and 63.

is itself such a decision where it produces legal effects or similarly significantly affects that person.¹¹

The Court emphasised that a restrictive reading of Article 22 GDPR would risk circumvention, and with it a gap in legal protection, where the decision-making process is divided between several entities; the broad concept of decision strengthens the provision's effective protection and must cover the element of the process that determines the final result.¹²

III. AUTOMATED DECISION-MAKING AND ITS RATIO LEGIS

Under Article 22 GDPR, individuals may object to decisions based solely on automated processing – including profiling – where such decisions produce legal effects or comparably affect them.¹³

The ratio legis is to protect the individual against the risks of delegating significant decisions to algorithms operating without human oversight.¹⁴

In Polish literature, M Kupiec finds this interpretation controversial: the functional understanding of 'decision' blurs the boundary between stages of the decision-making process.¹⁵ The criticism, though worth attention dogmatically, does not fully account for the teleological premises of the ruling.¹⁶

Medical AI sharpens the stakes. As G Sibiga observes, Article 22 covers not just final decisions but any step in the process that effectively determines the outcome.¹⁷ In medical diagnostics, the algorithmic result – formally only a recommendation – may de facto determine further clinical proceedings.

¹¹ SCHUFA (n 1), operative part, point 1.

¹² SCHUFA (n 1), paras 60–62.

¹³ Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data [2016] OJ L119/1 (GDPR), Art 22(1).

¹⁴ Grzegorz Sibiga, 'Zautomatyzowane podejmowanie decyzji na podstawie RODO' (2022) 21 *Monitor Prawniczy* 1143.

¹⁵ Mateusz Kupiec, 'Nowe spojrzenie na zautomatyzowane podejmowanie decyzji w rozumieniu art 22 RODO – glosa do wyroku TS z 7.12.2023 r, C-634/21' (2024) 3 *Europejski Przegląd Sądowy* 33.

¹⁶ Kupiec (n 15) 35.

¹⁷ Sibiga (n 14) 1144.

Automation bias – the well-documented tendency to defer to computer outputs without scrutiny – makes this worse.¹⁸ A physician who formally retains authority may in practice simply accept what the algorithm says; the nominal two-step process collapses into one – precisely the scenario Article 22 was designed to address.

IV. IMPLICATIONS OF THE SCHUFA JUDGMENT FOR MEDICAL LAW

1. THE PATIENT’S RIGHT TO INFORMATION IN ALGORITHMIC MEDICINE

The right to information, regulated in Article 9 of the Patient Rights and Patient Ombudsman Act¹⁹ and Article 31 of the Act on the Professions of Physician and Dentist,²⁰ is a precondition for valid consent. As D Karkowska puts it, information typically comes first – only after receiving it can the patient give meaningful consent;²¹ consent without prior information is not valid.²²

Under Article 31(1) of the Medical Professions Act, a physician must provide comprehensible information about the patient’s state of health, diagnosis, proposed and possible diagnostic and therapeutic methods, foreseeable consequences of their application or non-application, treatment results, and prognosis. M Malczewska is right that meeting this duty lets the patient exercise self-determination and take an active part in treatment.²³ The duty is not only legal but also ethical, now expressed in Article 14(2) of the Code of Medical Ethics.^{24 25}

After SCHUFA, must physicians also inform patients when AI is involved in diagnosis or treatment? There are good reasons to think so. First, AI use counts as a diagnostic method within the meaning of Article 31(1), about which the patient

¹⁸ Linda J Skitka, Kathleen L Mosier and Mark Burdick, ‘Does automation bias decision-making?’ (1999) 51 *International Journal of Human-Computer Studies* 991.

¹⁹ Patient Rights and Patient Ombudsman Act of 6 November 2008 [2024] JoL 581, consolidated text (Ustawa o prawach pacjenta i Rzeczniku Praw Pacjenta).

²⁰ Act of 5 December 1996 on the Professions of Physician and Dentist [2024] JoL 1287, consolidated text (Ustawa o zawodach lekarza i lekarza dentysty).

²¹ Karkowska (n 2).

²² Karkowska (n 2).

²³ Malczewska (n 4).

²⁴ Malczewska (n 4).

²⁵ Polish Code of Medical Ethics (Kodeks Etyki Lekarskiej), as amended from 1 January 2025, Art 14(2) <https://nil.org.pl/uploaded_images/1723037323_kel-2305.pdf> accessed 20 January 2026.

should be informed.²⁶ Second, AI systems work probabilistically and often opaquely (the ‘black box’ problem) – facts a patient may well want to know before consenting.

L Caban indicates that information must be adapted in form and content to the perceptual capabilities of the given patient;²⁷ a uniform, objective standard would be unjustified, since the abilities of patients differ.²⁸ With algorithms, comprehensibility matters even more: the patient needs some grasp of the AI’s role in their care.

2. MODELS OF INFORMING THE PATIENT

Scholarship recognizes three models of the information owed:²⁹ the reasonable physician model, under which the physician decides according to professional standards; the reasonable patient model, an objective standard of what a reasonable person in the patient’s situation would need; and the subjectivist model, focused on individual needs³⁰. Polish law mixes them: the fixed catalogue of Article 31(1), supplemented by information owed at the patient’s request.³¹ As M Guzowska indicates, information must be comprehensible – adapted to the patient’s intellectual capabilities.³²

The reasonable patient model needs updating for AI. A contemporary patient, aware that healthcare is increasingly digital, may well expect to be told whether algorithms are used, how they work, and what can go wrong. This finds support in case law,³³ which ties the scope of the duty to what a reasonable person in the patient’s situation objectively needs in order to take an informed and prudent decision.³⁴

The comparative argument points the same way. In *Montgomery v Lanarkshire Health Board*, the UK Supreme Court rebuilt the duty of disclosure around the reasonable patient: ‘The test of materiality is whether, in the circumstances of the particular case, a reasonable person in the patient’s position would be likely to attach significance to the risk, or the doctor is or should reasonably be aware that

²⁶ Malczewska, comment 12 to Art 31 in Zielińska (n 4).

²⁷ Łukasz Caban, comment 10 to art 31 in Marcin Kopec (ed), *Ustawa o zawodach lekarza i lekarza dentystry. Komentarz*, LEX/el. (Warszawa 2016).

²⁸ Caban (n 27).

²⁹ Mariola Guzowska, ‘Prawo pacjenta do informacji o stanie zdrowia jako jedno z praw przysługujących w procesie leczenia’ (2009) 9 Przegląd Sądowy 93.

³⁰ Guzowska (n 29) 94–95.

³¹ Guzowska (n 29) 95.

³² Guzowska (n 29) 97.

³³ Case I ACa 236/05 29 September 2005 Court of Appeal in Poznań (Sąd Apelacyjny w Poznaniu).

³⁴ Case II CSK 117/10 8 July 2010 Supreme Court of Poland (Sąd Najwyższy).

the particular patient would be likely to attach significance to it'.³⁵ Materiality cannot be reduced to percentages.³⁶ On that test, the involvement of an opaque algorithm in a diagnosis is hard to dismiss as immaterial: it bears on the character of the recommendation, its error profile, and the patient's ability to question it.

3. INFORMED CONSENT IN THE ERA OF ALGORITHMIC MEDICINE

Informed consent is bedrock medical law – the legal expression of respect for patient autonomy. Information must be prior, individualised, and understandable.³⁷

SCHUFA's core lesson is that Article 22 cannot be evaded by splitting decisions across entities.³⁸ Transposed to medical law, consent to the use of AI in the diagnostic and therapeutic process must be informed in the sense that the patient knows the algorithm's role in decisions concerning their health.

This departs markedly from the position taken elsewhere. Cohen concludes that under American law, in general, liability will not lie for failing to inform the patient that an AI/ML system helped formulate the treatment recommendation: the disclosure duty, tied to the risks of the proposed treatment itself, does not reach the process by which the recommendation was generated.³⁹ Cohen and Slottje likewise treat judgments about an AI system's reliability as the kind of trust that the patient places in the physician's hands.⁴⁰ Hatherley presses the normative point: the four standard arguments for disclosure – from risk, from rights, from materiality, from autonomy – all fail, and mandatory disclosure could even harm patients by giving stakeholders a way to avoid accountability for harm from improper uses of these systems.⁴¹

These objections deserve an answer, and three can be given. First, the statutory text differs: Article 31(1) expressly lists 'proposed and possible diagnostic and therapeutic methods' among the mandatory items of information, and a diagnostic

³⁵ *Montgomery v Lanarkshire Health Board* [2015] UKSC 11 [87].

³⁶ *Montgomery v Lanarkshire Health Board* (n 35) [89].

³⁷ Jolanta Budzowska, comment 5 to art 14 in Radosław Tymiński (ed), *Kodeks Etyki Lekarskiej. Komentarz, LEX/el.* (Warszawa 2025).

³⁸ SCHUFA (n 1) paras 60–62.

³⁹ Cohen (n 5) 1428 and 1434.

⁴⁰ Cohen and Andrew Slottje, 'Artificial Intelligence and the Law of Informed Consent' in B Solaiman and IG Cohen (eds), *Research Handbook on Health, AI and the Law* (Cheltenham 2024) 181.

⁴¹ Hatherley (n 6).

method includes the pathway by which the diagnosis is reached. The interpretive space that lets American courts treat AI as an invisible input does not exist here. Secondly, Hatherley's rebuttal of the autonomy argument treats the algorithm as one more assistive input, like a journal article or a colleague's advice; under Polish law, and after SCHUFA under EU law as well, the information serves the patient's self-determination, which extends to the decision-making process itself – including who, or what, is doing the deciding. Thirdly, materiality is an empirical question, and the record speaks against the sceptics: in a 2025 radiology survey, 91.1% of patients wanted to be informed about AI use in their imaging and as many wanted the right to opt out.⁴² A circumstance that nine patients out of ten declare significant is material on any reasonable-patient standard.

Does a general consent to treatment cover AI use, or must AI be disclosed separately? The better view is that disclosure is required. First, AI changes the risk profile: these systems make distinctive kinds of errors (algorithmic bias, for example).⁴³ Second, the patient may hold justified worldview beliefs about the role of humans in medical decisions. Third, SCHUFA requires that data subjects be aware of the algorithm's role in decisions concerning them.⁴⁴

M Nesterowicz, commenting on the judgment of the Court of Appeal in Szczecin of 11 August 2016, stressed that the right to information ranks among the most important patient rights.⁴⁵ Damages were awarded there, although no physical harm was shown: losing the chance to direct one's own treatment is itself a cognizable harm.⁴⁶ The same logic applies to AI – withholding the information violates the patient's rights, even if the algorithm got the diagnosis right.

V. DAMAGES FOR VIOLATION OF PATIENT RIGHTS

Under Article 4(1) of the Patient Rights Act, damages may be awarded for breach of patient rights even without proof of physical injury;⁴⁷ the basis is Article 448 of

⁴² Kennedy N McGhee and others, 'Patient Preferences for Artificial Intelligence in Medical Imaging: A Single-Center Cross-Sectional Survey' (2025) *Journal of Imaging Informatics in Medicine* 1, doi 10.1007/s10278-025-01629-w.

⁴³ Ziad Obermeyer and others, 'Dissecting racial bias in an algorithm used to manage the health of populations' (2019) 366 *Science* 447.

⁴⁴ SCHUFA (n 1), paras 56 and 63.

⁴⁵ Mirosław Nesterowicz, 'Prawo pacjenta do informacji – glosa do wyroku SA z 11.08.2016 r, I ACa 300/16' (2020) 2 *Orzecznictwo Sądów Polskich*, item 11.

⁴⁶ *Ibid.*

⁴⁷ Patient Rights and Patient Ombudsman Act (n 19), Art 4(1).

the Civil Code.⁴⁸ Case law confirms that the provider's liability turns solely on the violation of a patient's right specified in the Act and fault;⁴⁹ the Court of Appeal in Katowice (judgment of 10 March 2021) awarded PLN 40,000 for violation of the right to information.⁵⁰

For AI-assisted medicine, the upshot is clear: failing to tell the patient about the algorithm can ground liability on its own, regardless of whether the diagnosis was correct. As D Karkowska indicates, the patient has the right to the full spectrum of knowledge about their state of health.⁵¹

VI. THE REGULATORY FRAMEWORK FOR ALGORITHMIC MEDICINE

1. THE AI ACT, MDR, AND GDPR

Regulation (EU) 2024/1689 (AI Act)⁵² places diagnostic AI in healthcare in the high-risk category,⁵³ with stricter requirements for risk management, documentation, transparency, and human oversight. Under Article 14, high-risk systems must be designed so that effective human oversight is possible⁵⁴ – a design requirement addressed to providers, not an operational duty of supervision; in Polish law, that duty rests on the physician under Article 12(4) of the Code. Under Article 13(1), such systems must be transparent enough for deployers to interpret the output and use it appropriately.⁵⁵ That is transparency of use, not of mechanism; the residual opacity – why a particular output was produced – is what matters for consent and proof. Software using AI algorithms for diagnostic purposes is also a medical device under the Medical Devices Regulation,⁵⁶ and its placing on the market requires an appropriate conformity assessment procedure.⁵⁷

⁴⁸ Case V ACa 683/13 5 February 2014 Court of Appeal in Katowice (Sąd Apelacyjny w Katowicach).

⁴⁹ Malczewska, comment 25 to Art 31 in Zielińska (n 4).

⁵⁰ Case I ACa 1009/19 10 March 2021 Court of Appeal in Katowice (Sąd Apelacyjny w Katowicach).

⁵¹ Karkowska, comment 4 to Art 9 in Karkowska (n 2).

⁵² Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence [2024] OJ L 2024/1689 (AI Act).

⁵³ AI Act (n 52), Art 6(1) in conjunction with Annex III, point 1.

⁵⁴ AI Act (n 52), Art 14.

⁵⁵ AI Act (n 52), Art 13(1).

⁵⁶ Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices [2017] OJ L117/1 (MDR).

⁵⁷ See MDCG 2019-11, Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745 and Regulation (EU) 2017/746.

2. ARTICLE 12 OF THE CODE OF MEDICAL ETHICS AS A BREAKTHROUGH IN POLISH MEDICAL DEONTOLOGY

The key provision for Polish physicians is Article 12 of the Code of Medical Ethics, effective 1 January 2025⁵⁸ – the first provision of Polish medical ethics to deal with AI. A physician may use artificial intelligence algorithms in diagnostic, therapeutic, or preventive procedures provided that: (1) the patient is informed that artificial intelligence will be used in making the diagnosis or in the therapeutic process; (2) the patient's informed consent to its application is obtained; (3) the algorithms used are approved for medical use and possess appropriate certificates; (4) the final diagnostic and therapeutic decision is always made by the physician.

Article 12(4), requiring that the final clinical decision always rests with the physician,⁵⁹ restates basic medical ethics and gives operational content to the design-level oversight requirement of Article 14 of the AI Act. But formal human oversight does not eliminate automation bias – which is why informed consent matters. J Budzowska is blunt: the duties in Article 12(1)–(3) may be impossible, pointless, or counterproductive to satisfy, and there is a risk of disciplinary proceedings based on them being abusive.⁶⁰

3. CRITICAL ANALYSIS OF ARTICLE 12(3) OF THE CODE AND PRACTICAL ENFORCEABILITY

Article 12(3) requires that the physician use only artificial intelligence algorithms that are ‘approved for medical use’ and possess ‘appropriate certificates’. The intention – protecting patients from untested tools – is sound, but the rule raises serious enforceability problems. As J Budzowska notes, for lack of a definition of ‘appropriate’ this duty may be perceived as both unenforceable and unexecutable;⁶¹ likewise, the requirement of algorithms ‘approved for medical use’ is impossible to fulfil, because the legal concept of such approval is unknown.⁶² She is not alone: J Pawlikowski finds the restrictions of Article 12 difficult to apply in practice and potentially over-restrictive,⁶³ and Piłśniak and co-authors observe

⁵⁸ Polish Code of Medical Ethics (n 25), Art 12.

⁵⁹ Polish Code of Medical Ethics (n 25), Art 12(4).

⁶⁰ Budzowska, comment 3 to Art 12 in Tymiński (n 37).

⁶¹ Budzowska, comment 5.3 to Art 12 in Tymiński (n 37).

⁶² Ibid.

⁶³ Jakub Pawlikowski, ‘Znowelizowany Kodeks etyki lekarskiej. Komentarz’ (2025) *Medycyna Praktyczna* 7–8 (supplement).

that no standardised procedures exist by which AI tools could obtain uniform, officially approved certificates.⁶⁴

The problem is acute for large language models – ChatGPT, Claude, Gemini. They are not certified as medical devices, yet physicians already use them to think through cases, look up information, or draft patient-friendly explanations; in the American Medical Association’s 2026 survey, 81% of physicians reported awareness or use of AI in their practice.⁶⁵ Read literally, Article 12(3) would make it unethical ever to consult an uncertified chatbot in the course of patient care.

That cannot be right: using a chatbot to check drug interactions is no more unethical than using a search engine or phoning a colleague. What matters is not whether AI is used, but how.

This critique is convincing, but it stops at the diagnosis: the provision, as drafted, is unworkable. The more interesting question – answered here on the article’s own account – is whether Article 12(3) can be given a workable meaning *de lege lata*. It can, provided one accepts that the provision regulates the manner in which the physician uses artificial intelligence, not the tool as such: certification attaches to a mode of use, not to a class of software.

On this reading, the distinction between diagnostic AI and cognitive AI does real doctrinal work, and it can be operationalised. Three criteria mark the boundary. The first is directness of influence: does the output feed into a decision concerning an identified patient, or merely inform the physician’s general understanding of a problem? The second concerns the data: has the physician passed the patient’s data to the system in an identifiable form, or is the query abstract? The third turns on the form of the output: a recommendation for the case at hand, or general knowledge that the physician must still apply on her own responsibility?

The official commentary of the Ethics Committee of the Supreme Medical Council reads Article 12 the same way: where the algorithm is of key importance for the health service provided, informing the patient and obtaining consent are required; where the system merely supports the physician’s work, consent is not required and disclosure is only recommended.⁶⁶ The mode of use, not the technology, carries the duties.

⁶⁴ Joanna A Piłśniak and others, ‘Zastosowanie algorytmów sztucznej inteligencji w praktyce lekarskiej w świetle nowelizacji Kodeksu Etyki Lekarskiej’ (2025) 31(3) *Medycyna Ogólna i Nauki o Zdrowiu* 156, 158.

⁶⁵ American Medical Association, 2026 Physician Survey on Augmented Intelligence (AMA Center for Digital Health and AI, March 2026) 5.

⁶⁶ Komentarz Komisji Etyki Lekarskiej Naczelnej Rady Lekarskiej do art 12 znowelizowanego Kodeksu Etyki Lekarskiej. Sztuczna inteligencja (Naczelna Izba Lekarska 2024) 2.

Where all three point the first way, the physician uses AI in the diagnostic and therapeutic process within the meaning of Article 12, and all four of its conditions apply: disclosure, consent, certification, and the final human decision. An algorithm reading a CT scan is the paradigm case; certification there maps onto the conformity assessment that the MDR and the AI Act already demand. Where all three point the second way – a general question, stripped of identifying detail, verified against transparent sources, decided alone – the tool functions as a textbook, a search engine, or a colleague consulted by telephone. Article 12 does not reach this knowledge mode; it is governed by the ordinary duties of professional diligence and secrecy. Requiring certification here would make as much sense as certifying textbooks.

Between the two lies a grey zone, and it is the dangerous one: feeding a general-purpose chatbot the data of a concrete patient and acting on its answer. That use combines the defects of both modes – no certification of the tool, no detachment of the physician – and on the reading proposed here, it is impermissible without qualification. The outer boundary of the knowledge mode is data protection law: the patient's data must be anonymised, not merely pseudonymised, before any fragment of the case reaches a third-party model.⁶⁷ A physician who submits identifiable data has left the knowledge mode and very probably breached professional secrecy.

The distinction also settles the scope of the duty to inform. In the decisional mode, AI use must be disclosed and consented to: it is a feature of the diagnostic method under Article 31(1), and after SCHUFA, its concealment cannot be cured by the physician's formal signature. In the knowledge mode, no disclosure duty arises: a physician does not inform the patient about the textbooks she has read or the colleagues she has consulted, and an anonymised query to a language model belongs to the same class. Requiring disclosure there would trivialise the information right and weaken the one disclosure that matters.

Budzowska herself concedes that Article 12 needs rewriting – to clear up terminological confusion, clarify physician duties, and define terms properly.⁶⁸ The three criteria proposed above could serve as its starting point; until then, they allow the provision to be applied sensibly rather than suspended in practice.

⁶⁷ GDPR (n 13), recital 26, Arts 4(1) and (5).

⁶⁸ Budzowska, comment 6 to Art 12 in Tymiński (n 37).

4. THE GDPR AND THE PROCESSING OF HEALTH DATA BY AI SYSTEMS

The GDPR applies in full to AI processing of health data. Health data are a special category (Article 9),⁶⁹ processing of which is in principle prohibited, subject to the exceptions of Article 9(2). As P Fajgielski indicates, data concerning health encompasses all information about the past, present, or future state of a person's physical or mental health.⁷⁰ Does consent to treatment imply consent to automated processing? SCHUFA suggests not: the data subject must know when decisions are made algorithmically,⁷¹ which supports separate consent.

4.1 THE RIGHT TO HUMAN CONTACT AS THE LIMIT OF ALGORITHMISATION

SCHUFA, the AI Act's human oversight requirements, and Article 12(4) of the Code together support a distinct patient right to human contact in algorithmic medicine: the right to receive a diagnosis from a human physician rather than solely from an algorithm, to speak with a physician in case of doubts, and to request a second human opinion.

The idea has support in the literature, with a telling difference. Ploug and Holm argue for a right to a second opinion on AI-supported diagnosis – but would allow it to be satisfied by another, independent AI system.⁷² That may suffice where the worry is accuracy; where it is the absence of a human interlocutor, only a human answers it. Ploug and his co-authors have since argued that risk-based regulation must be supplemented by specific individual patient rights;⁷³ the right to human contact proposed here is such a right.

Patients leave little doubt. In a survey of 13,806 patients from 74 hospitals in 43 countries, 72.9% preferred the physician to make the final diagnostic decision, and 70.2% preferred explainable AI even at some cost to accuracy;⁷⁴ in the radiology survey already cited, 91.1% wanted disclosure and as many the right to opt out.⁷⁵ Patients accept AI as an instrument and refuse it as a counterpart.

⁶⁹ GDPR (n 13), Art 9(2).

⁷⁰ Paweł Fajgielski, comment 12 to art 9 in Paweł Fajgielski, *Ogólne rozporządzenie o ochronie danych. Komentarz*, LEX/el. (Warszawa 2022).

⁷¹ SCHUFA (n 1), paras 56 and 63.

⁷² Thomas Ploug and Søren Holm, 'The right to a second opinion on Artificial Intelligence diagnosis – Remedying the inadequacy of a risk-based regulation' (2023) 37 *Bioethics* 303.

⁷³ Ploug and others (n 7) 1–2.

⁷⁴ Felix Busch and others, 'Multinational Attitudes Toward AI in Health Care and Diagnostics Among Hospital Patients' (2025) 8(6) *JAMA Network Open* e2514452, 1.

⁷⁵ McGhee and others (n 42) 1.

The patient, an autonomous subject, has the right to a relationship with another autonomous subject – a human physician – not merely to being an object of processing by an algorithm.

Such a right finds support in the constitutional guarantee of human dignity (Article 30 of the Polish Constitution)⁷⁶ and in Article 22 GDPR. Dignity, in the Kantian formula behind both provisions, means being treated always as an end and never merely as a means⁷⁷ – not as raw material for an algorithm.

4.2 LIABILITY FOR HARM IN ALGORITHMIC MEDICINE

The duty to inform is one half of patient protection; liability for harm is the other. De lege lata, Polish law offers three routes: fault-based liability of the physician (Article 415 of the Civil Code), liability of the healthcare entity (Article 430), and product liability directed at the producer.⁷⁸ Independently, Article 4(1) of the Patient Rights Act compensates for the very violation of the right to information, without proof of bodily harm (section IV.4).

Each route is strained by the same feature of the technology: opacity. As Duffourc and Gerke observe, black-box systems ‘operate without transparency, making it difficult or even impossible to understand how they arrive at a particular result’.⁷⁹ A claimant who must prove fault or causation faces an evidentiary wall: what makes the algorithm clinically useful makes its failure forensically invisible.

The physician’s position turns on the standard of care, and that standard is a moving target. ‘Malpractice law is at base conservative’, Price, Gerke and Cohen observe: it ‘typically will find no liability for following the standard of care’;⁸⁰ that conservatism today shields the physician who ignores an AI recommendation. But the same authors note that ‘as AI systems become more prevalent, following AI advice may itself be incorporated into the standard of care, such that ignoring the advice would render a physician liable for resulting injury’.⁸¹ Legal risk can, therefore, reverse direction over time.

⁷⁶ Constitution of the Republic of Poland, Art 30.

⁷⁷ Immanuel Kant, *Groundwork of the Metaphysics of Morals* (first published 1785, M Gregor (tr), CUP 1998) 38.

⁷⁸ Act of 23 April 1964 – Civil Code [2025] JoL 1071, consolidated text (kodeks cywilny), Arts 415, 430, 449(1)– 449(11).

⁷⁹ Mindy Duffourc and Sara Gerke, ‘Decoding U.S. Tort Liability in Healthcare’s Black-Box AI Era: Lessons from the European Union’ (2024) 27 *Stanford Technology Law Review* 1, 2.

⁸⁰ W Nicholson Price II, Gerke and Cohen, ‘Liability for Use of Artificial Intelligence in Medicine’ in B Solaiman and IG Cohen (eds), *Research Handbook on Health, AI and the Law* (Cheltenham 2024) 153.

⁸¹ *Ibid* 153.

The EU legislature has answered half of the problem. Directive (EU) 2024/2853 states in terms that software, including AI systems, is a product for the purposes of no-fault liability,⁸² and gives claimants two instruments aimed at the black-box difficulty: disclosure of evidence held by the defendant (Article 9) and rebuttable presumptions of defectiveness and causation where proof would be excessively difficult for technical or scientific complexity (Article 10).⁸³ Transposition is due by 9 December 2026.⁸⁴

The other half did not survive: the proposed AI Liability Directive, which would have eased fault-based claims, was withdrawn by the Commission in October 2025 for lack of foreseeable agreement.⁸⁵ What remains is an asymmetry: harmonised, claimant-friendly rules against the producer; unharmonised national rules, with the full burden of proving fault and causation, against the physician and the hospital – although harm from medical AI typically materialises through a clinical decision, not a manufacturing defect.

Liability and consent are not separate compartments. Non-disclosure of AI involvement grounds a claim under Article 4(1) of the Patient Rights Act on its own; in a harm action, a patient who proves he/she would have refused the algorithmic pathway if properly informed converts the omitted disclosure into the first link of the causal chain.

VII. PROPOSALS DE LEGE FERENDA

Several reforms follow from this analysis.

First, it is proposed to amend Article 31 of the Medical Professions Act by expressly indicating that the information duty includes information about AI use in the diagnostic and therapeutic process; the amendment would codify the interpretation defended in section IV.

Second, it is proposed to introduce into the Patient Rights Act a provision establishing the right to human contact in algorithmic medicine, comprising: (1) the

⁸² Directive (EU) 2024/2853 of the European Parliament and of the Council of 23 October 2024 on liability for defective products and repealing Council Directive 85/374/EEC [2024] OJ L, 2024/2853, recital 13 and Art 4(1).

⁸³ Directive (EU) 2024/2853 (n 82), Arts 9 and 10.

⁸⁴ Directive (EU) 2024/2853 (n 82), Art 22(1).

⁸⁵ Withdrawal of Commission proposals [2025] OJ C, C/2025/5423; the withdrawn proposal: COM(2022) 496 final (AI Liability Directive); reasons in COM(2025) 45 final.

right to receive an explanation of the algorithmic diagnosis from a physician; (2) the right to request verification of the diagnosis by a human physician; (3) the right to object to the use of AI in certain aspects of the treatment process.

The right to verification may seem redundant: health services may be provided only by authorised professionals, and Article 12(4) reserves the final decision to the physician. But a systemic guarantee is not an individual claim: given automation bias, formal authorship does not ensure substantive re-examination, and the proposed right lets the patient demand genuine verification, backed by Article 4(1) of the Patient Rights Act.

The last of these elements – the right to object – invites an obvious objection: is this not a licence to demand medicine without algorithms, much as a patient might demand bloodletting? The analogy fails but in an instructive way. A patient who objects to AI does not ask for an obsolete treatment; he/she asks for the same service in its human variant – today the professional standard, not a museum piece. As long as a *lege artis* human-performed alternative exists, honouring the objection demands nothing that medicine is entitled to refuse.

The right cannot, however, be absolute, and the analogy becomes apt precisely where it stops being rhetorical: when a validated algorithmic method has become the standard of care and the human-only variant has fallen below it – the trajectory described by Price, Gerke and Cohen.⁸⁶ A physician asked to bypass the algorithm is then being asked to provide substandard care, which the patient cannot demand and the physician must refuse. The protection changes form rather than disappears: the veto gives way to human verification and explanation of the algorithmic output and, at the limit, to the general right to refuse treatment. Between those poles, the weight of the objection should track the stakes: strongest where the decision is irreversible or existential, weakest where it is routine and reversible. So construed, the right to object is not a brake on algorithmic medicine; it is the price of its legitimacy.

Third, it is proposed to clarify the prerequisites of liability for damage caused by medical AI. Transposition of Directive (EU) 2024/2853 will modernise the claim against the producer; the asymmetry described in section VII argues for a parallel easing of the claimant's evidentiary position against healthcare providers, for instance by extending disclosure duties and presumptions analogous to Articles 9 and 10 to claims arising from the clinical use of AI. Otherwise, the injured patient will be procedurally better armed against a distant software house than against the hospital that treated him.

⁸⁶ Price, Gerke and Cohen (n 80) 153.

Fourth, it is proposed to redraft Article 12 of the Code of Medical Ethics, distinguishing between AI used directly in the diagnostic and therapeutic process, and AI used as a cognitive tool of the physician – the three criteria proposed in section V.3 offer a drafting template. Otherwise, the provision remains unworkable or produces absurd results.

VIII. CONCLUSIONS

SCHUFA is now a reference point for any discussion of AI and law in medicine: AI used in diagnosis or treatment may fall under Article 22 even where the physician nominally retains authority, so long as the algorithm's output effectively determines the outcome.

The ruling matters in three ways. On information duties, it supports including AI use among the facts patients must be told. On consent, it makes plain that patients should know when algorithms shape their care. On liability, it favours a broad view of causation between AI output and harm – a view the new Product Liability Directive backs with presumptions, even as the withdrawal of the AI Liability Directive leaves claims against physicians to national law.

Polish law is ahead of the comparative field rather than behind it. Where American doctrine would tolerate silent AI, and part of the bioethics literature would justify that silence, Article 12 of the Code of Medical Ethics expressly requires disclosure and consent. The certification requirement, as drafted, may be unworkable; the distinction between diagnostic AI and cognitive AI, operationalised through three criteria, allows it to be applied *de lege lata* and offers a template for reform.

The Supreme Court has grounded the duty to disclose treatment risks in Article 31(1) of the Medical Professions Act;⁸⁷ extending it to AI risks will take effort from lawmakers and the profession alike. SCHUFA and Article 12 are steps in that direction.

REFERENCES

American Medical Association, *2026 Physician Survey on Augmented Intelligence* (AMA Center for Digital Health and AI, March 2026)

⁸⁷ Case II CSK 259/08 7 November 2008 Supreme Court of Poland (Sąd Najwyższy).

Budzowska J, comments to Art 12 and Art 14 in R Tymiński (ed), *Kodeks Etyki Lekarskiej. Komentarz*, LEX/el. (Warszawa 2025)

Busch F and others, 'Multinational Attitudes Toward AI in Health Care and Diagnostics Among Hospital Patients' (2025) 8(6) JAMA Network Open e2514452

Caban Ł, comment to Art 31 in M Kopeć (ed), *Ustawa o zawodach lekarza i lekarza dentystry. Komentarz*, LEX/el. (Warszawa 2016)

Cohen IG, 'Informed Consent and Medical Artificial Intelligence: What to Tell the Patient?' (2020) 108 Georgetown Law Journal 1425

Cohen IG, Slottje A, 'Artificial Intelligence and the Law of Informed Consent' in B Solaiman and IG Cohen (eds), *Research Handbook on Health, AI and the Law* (Cheltenham 2024)

Duffourc M, Gerke S, 'Decoding U.S. Tort Liability in Healthcare's Black-Box AI Era: Lessons from the European Union' (2024) 27 Stanford Technology Law Review 1

Fajgielski P, *Ogólne rozporządzenie o ochronie danych. Komentarz*, LEX/el. (Warszawa 2022)

Guzowska M, 'Prawo pacjenta do informacji o stanie zdrowia jako jedno z praw przysługujących w procesie leczenia' (2009) 9 Przegląd Sądowy 91

Hatherley J, 'Are clinicians ethically obligated to disclose their use of medical machine learning systems to patients?' (2025) 51 Journal of Medical Ethics 567

Kant I, *Groundwork of the Metaphysics of Morals* (first published 1785, M Gregor (tr), CUP 1998)

Karkowska D, comments to Art 9 in D Karkowska (ed), *Prawa pacjenta i Rzecznik Praw Pacjenta. Komentarz*, LEX/el. (Warszawa 2021)

Komentarz Komisji Etyki Lekarskiej Naczelnej Rady Lekarskiej do art 12 znowelizowanego Kodeksu Etyki Lekarskiej. Sztuczna inteligencja (Naczelna Izba Lekarska 2024)

Kupiec M, 'Nowe spojrzenie na zautomatyzowane podejmowanie decyzji w rozumieniu art 22 RODO - glosa do wyroku TS z 7.12.2023 r, C-634/21' (2024) 3 Europejski Przegląd Sądowy 33

Malczewska M, comments to Art 31 in E Zielińska (ed), *Ustawa o zawodach lekarza i lekarza dentystry. Komentarz*, LEX/el. (Warszawa 2022)

McGhee KN and others, 'Patient Preferences for Artificial Intelligence in Medical Imaging: A Single-Center Cross-Sectional Survey' (2025) Journal of Imaging Informatics in Medicine, doi 10.1007/s10278-025-01629-w

Nesterowicz M, 'Prawo pacjenta do informacji – glosa do wyroku SA z 11.08.2016 r, I ACa 300/16' (2020) 2 Orzecznictwo Sądów Polskich, item 11

Obermeyer Z and others, 'Dissecting racial bias in an algorithm used to manage the health of populations' (2019) 366 Science 447

Pawlikowski J, 'Znowelizowany Kodeks etyki lekarskiej. Komentarz' (2025) 7-8 Medycyna Praktyczna (supplement)

Piłśniak JA and others, 'Zastosowanie algorytmów sztucznej inteligencji w praktyce lekarskiej w świetle nowelizacji Kodeksu Etyki Lekarskiej' (2025) 31(3) *Medycyna Ogólna i Nauki o Zdrowiu* 156

Ploug T, Holm S, 'The right to a second opinion on Artificial Intelligence diagnosis – Remediating the inadequacy of a risk-based regulation' (2023) 37 *Bioethics* 303

Ploug T and others, 'The need for patient rights in AI-driven healthcare – risk-based regulation is not enough' (2025) *Journal of the Royal Society of Medicine* (online first), doi 10.1177/01410768251344707

Price WN II, Gerke S, Cohen IG, 'Liability for Use of Artificial Intelligence in Medicine' in B Solaiman and IG Cohen (eds), *Research Handbook on Health, AI and the Law* (Cheltenham 2024)

Sibiga G, 'Zautomatyzowane podejmowanie decyzji na podstawie RODO' (2022) 21 *Monitor Prawniczy* 1143

Skitka LJ, Mosier KL, Burdick M, 'Does automation bias decision-making?' (1999) 51 *International Journal of Human-Computer Studies* 991