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Το Περιοδικό "ΒΙΟΗΘΙΚΑ"

Το Περιοδικό "ΒΙΟΗΘΙΚΑ" αποτελεί ηλεκτρονική έκδοση της Εθνικής Επιτροπής Βιοηθικής & Τεχνοηθικής. Τα θεματικά του ενδιαφέροντα καλύπτουν όλο το φάσμα της σύγχρονης βιοηθικής και τεχνοηθικής. Για τον λόγο αυτό, καλούμε όχι μόνο καθιερωμένους αλλά κυρίως νέους επιστήμονες να στείλουν τις συμβολές τους.

Σκοπός του Περιοδικού είναι η ενημέρωση και η ανταλλαγή απόψεων και γνώσεων μεταξύ των επιστημόνων όλων των κλάδων με ιδιαίτερο θεωρητικό ή πρακτικό ενδιαφέρον για θέματα που αφορούν στη Βιοηθική αλλά και τα ηθικά ζητήματα της τεχνολογίας. Για την επίτευξη αυτού του σκοπού, στο Περιοδικό δημοσιεύονται, στην ελληνική ή στις κύριες ευρωπαϊκές γλώσσες, εργασίες που αποτελούν Άρθρα Σύνταξης, Πρωτότυπες Εργασίες και Ανασκοπήσεις.

Οι Πρωτότυπες Εργασίες και οι Ανασκοπήσεις διαβιβάζονται ανώνυμα σε διεπιστημονική ομάδα τριών κριτών, οι οποίοι τις αξιολογούν. Μόνο όσες εργασίες λάβουν οριστική έγκριση από τους κριτές δημοσιεύονται στο Περιοδικό. Επισημαίνεται ότι οι απόψεις στα κείμενα εκφράζουν μόνο τους συγγραφείς.

Αναλυτικές πληροφορίες για το Περιοδικό "ΒΙΟΗΘΙΚΑ" θα βρείτε στην ιστοσελίδα του Εθνικού Κέντρου Τεκμηρίωσης (ΠΕΡΙΟΔΙΚΟ Bioethica).

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Άρθρο Σύνταξης

Ηθικές προκλήσεις στην Τεχνητή Νοημοσύνη στην εκπαίδευση: Σκέψεις από την ελληνική φιλοσοφία

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Λέξεις κλειδιά: Τεχνητή Νοημοσύνη, εκπαίδευση, παιδεία, ηθική, προκαταλήψεις, φιλοσοφία.

Ethical challenges of Artificial Intelligence in education: Insights from Greek philosophy

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Keywords: Artificial Intelligence, education, ethics, bias, philosophy, educators.

Η Τεχνητή Νοημοσύνη (ΤΝ) δείχνει να έχει τη δυνατότητα να αναδιαμορφώσει ταχύτατα το εκπαιδευτικό σύστημα, ανεξαρτήτως βαθμίδας, προσφέροντας ευκαιρίες σε μαθητές, εκπαιδευτικούς και γονείς για την εξατομίκευση της μάθησης, τη βελτίωση των αξιολογήσεων και την παροχή βαθύτερων αναλύσεων σχετικά με τις επιδόσεις των μαθητών. Καθώς, προοδευτικά, η εκπαιδευτική κοινότητα υιοθετεί αυτές τις τεχνολογίες, αναδεικνύονται και οι ηθικές επιπτώσεις αυτής της διαδικασίας που «υπόσχεται» πλατφόρμες προσαρμοστικής μάθησης, έξυπνα συστήματα διδασκαλίας και αυτοματοποιημένη βαθμολόγηση. Παράλληλα, η ενσωμάτωση τέτοιων εργαλείων εγείρει κρίσιμες ανησυχίες σχετικά με το απόρρητο των δεδομένων των μαθητών και των εκπαιδευτικών, την αλγοριθμική προκατάληψη (bias), και την αυτονομία και τον εξελισσόμενο ρόλο των εκπαιδευτικών.

Πολλά από τα διλήμματα που καλούμαστε να επιλύσουμε, μπορούν να αναλυθούν παραλληλίζοντας τις σύγχρονες εφαρμογές της ΤΝ στην εκπαίδευση με τις διαχρονικές ηθικές ιδέες που παρέχει η αρχαία ελληνική φιλοσοφία. Φιλόσοφοι όπως ο Σωκράτης, ο Πλάτωνας και ο Αριστοτέλης, τα έργα των οποίων έθεσαν τα θεμέλια της δυτικής σκέψης, προσφέρουν έναν μοναδικό «φακό» μέσα από τον οποίο μπορούμε να εξετάσουμε με κριτικό πνεύμα τις ηθικές προκλήσεις της ΤΝ στην εκπαίδευση. Αυτοί οι κλασικοί στοχαστές ασχολήθηκαν σε βάθος με ζητήματα γνώσης, ηθικής, ανθρώπινης ανάπτυξης και αυτονομίας, έννοιες που σχετίζονται άμεσα με τις προκλήσεις που αντιμετωπίζουμε σήμερα.

ΤΝ στην εκπαίδευση: ευχή και κατάρα

Οι τεχνολογίες Τεχνητής Νοημοσύνης υπόσχονται να φέρουν επαναστατικές αλλαγές στην εκπαίδευση με διάφορους τρόπους. Για παράδειγμα, οι εξατομικευμένες πλατφόρμες μάθησης προσαρμόζονται στις ατομικές ανάγκες κάθε μαθητή, επιλέγοντας το μαθησιακό περιεχόμενο και τον ρυθμό της διδασκαλίας ώστε να ταιριάζουν σε διαφορετικά στυλ και δυνατότητες μάθησης. Αναλύοντας τις τεράστιες ποσότητες δεδομένων που παράγει η χρήση ενός τέτοιου συστήματος από τους μαθητές, τα συστήματα αυτά μπορούν να εντοπίζουν κενά στις γνώσεις και να προτείνουν στοχευμένους μαθησιακούς πόρους, ενώ τα αυτοματοποιημένα συστήματα βαθμολόγησης μπορούν να μειώσουν τον διοικητικό φόρτο των εκπαιδευτικών, παρέχοντας ταχύτερη ανατροφοδότηση στους μαθητές, βελτιώνοντας ενδεχομένως και τα μαθησιακά αποτελέσματα. Επιπλέον, τα συστήματα διδασκαλίας με Τεχνητή Νοημοσύνη προσφέρουν εξατομικευμένη υποστήριξη στους μαθητές, βοηθώντας τους στην επίλυση προβλημάτων και απαντώντας σε ερωτήσεις εκτός των παραδοσιακών ωρών διδασκαλίας, χωρίς να χρειάζεται να απασχολείται ο εκπαιδευτικός.

Καθώς τα εκπαιδευτικά ιδρύματα και οι εταιρείες εκπαιδευτικής τεχνολογίες (ed-tech) συλλέγουν και αποθηκεύουν ευαίσθητες πληροφορίες, τα ερωτήματα σχετικά με την ιδιοκτησία των δεδομένων, την ασφάλεια και την πιθανή κατάχρηση γίνονται όλο και πιο σημαντικά. Επιπλέον, το ενδεχόμενο αλγοριθμικής μεροληψίας αποτελεί σημαντική απειλή για τη δικαιοσύνη στην εκπαίδευση: τα συστήματα ΤΝ είναι τόσο καλά, όσο τα δεδομένα στα οποία εκπαιδεύονται, και αν τα δεδομένα αυτά αντανακλούν τις υπάρχουσες κοινωνικές προκαταλήψεις, τα συστήματα αυτά μπορούν να διαιωνίσουν τις ανισότητες στην εκπαίδευση. Για παράδειγμα, εάν ένα αυτοματοποιημένο σύστημα εισαγωγής σε Πανεπιστήμια βάσει του βιογραφικού των μαθητών εκπαιδευτεί σε υπάρχοντα δεδομένα από περιζήτητα εκπαιδευτικά ιδρύματα, μπορεί να συνεχίσει να ευνοεί τις προνομιούχες ομάδες που ιστορικά έχουν ευκολότερη πρόσβαση σε αυτά, ενισχύοντας έτσι τις ανισότητες, αντί να τις εξαλείψει.

Επιπλέον, ενώ η ΤΝ μπορεί να ενισχύσει την εξατομίκευση, κινδυνεύει να υπονομεύσει τον ρόλο των εκπαιδευτικών. Η υποβάθμιση των διά ζώσης αλληλεπιδράσεων μαθητών και εκπαιδευτικών, που φάνηκε και από την περίοδο της πανδημίας ότι έχουν κρίσιμη σημασία για την κοινωνική και συναισθηματική ανάπτυξή τους, δημιουργεί τέτοιες ανησυχίες: αν δεν είμαστε προσεκτικοί, η εκπαίδευση μπορεί να γίνει υπερβολικά μηχανοποιημένη, δίνοντας προτεραιότητα στην αποδοτικότητα και τις μετρήσεις απόδοσης έναντι της ανάπτυξης της

κριτικής σκέψης, της δημιουργικότητας και της ηθικής κρίσης, δεξιότητες που δεν μπορούν εύκολα να ποσοτικοποιηθούν ή να αυτοματοποιηθούν.

Αρχαίες ελληνικές ιδέες στη σύγχρονη ηθική της τεχνητής νοημοσύνης

Οι προκλήσεις αυτές μπορεί να φαίνονται πρωτόγνωρες, αφού σχετίζονται με εργαλεία που μας έγιναν διαθέσιμα μόλις τα τελευταία χρόνια, αλλά αγγίζουν ηθικά ζητήματα που συζητούνται εδώ και χιλιετίες. Εδώ, οι αρχαίοι Έλληνες φιλόσοφοι μάς παρέχουν μια πληθώρα από ιδέες που παραμένουν εξαιρετικά επίκαιρες στην εποχή της ΤΝ. Ο Σωκράτης, για παράδειγμα, τόνισε τη σημασία της κριτικής σκέψης και του διαλόγου στην εκπαίδευση. Η Σωκρατική μαιευτική μέθοδος, η οποία περιλαμβάνει την υποβολή διερευνητικών ερωτήσεων για την ενθάρρυνση της βαθύτερης κατανόησης μιας έννοιας ή ενός φαινομένου, αφορά θεμελιωδώς την προώθηση της γνωσιακής αυτονομίας μαθητών και εκπαιδευτικών, σε αντιδιαστολή με την απλή παράθεση γεγονότων και εγκυκλοπαιδικών γνώσεων. Σε ένα εκπαιδευτικό περιβάλλον που κυριαρχείται από την Τεχνητή Νοημοσύνη, υπάρχει ο πραγματικός κίνδυνος οι μαθητές να γίνουν παθητικοί δέκτες πληροφοριών, βασιζόμενοι στην τεχνολογία για να δώσουν απαντήσεις, αντί να εμπλακούν στην ενεργή, στοχαστική αμφισβήτηση που πρότεινε ο Σωκράτης. Η ΤΝ, αν και είναι ικανή να επεξεργάζεται δεδομένα και να παρέχει εξατομικευμένες συστάσεις, δεν έχει τη διαφοροποιημένη ικανότητα (ακόμα, τουλάχιστον) να εμπλέκει τους μαθητές σε έναν διάλογο ανοικτού τύπου που να ενθαρρύνει την κριτική σκέψη. Ως εκπαιδευτικοί και υπεύθυνοι χάραξης πολιτικής, πρέπει να διασφαλίσουμε ότι τα εργαλεία ΤΝ θα χρησιμοποιούνται για να συμπληρώνουν και όχι να αντικαθιστούν αυτό το βασικό ανθρώπινο στοιχείο της εκπαίδευσης.

Αντίστοιχα, η Αλληγορία του σπηλαίου του Πλάτωνα αποτελεί μια άλλη ενδιαφέρουσα μεταφορά για έναν εκπαιδευτικό κόσμο που επαυξάνεται από την Τεχνητή Νοημοσύνη. Στην αλληγορία, οι φυλακισμένοι είναι αλυσοδεμένοι μέσα σε ένα σπήλαιο, βλέπουν μόνο σκιές στον τοίχο, οι οποίες δημιουργούνται από τους ανθρώπους έξω από αυτό και συγχέουν αυτές τις σκιές με την πραγματικότητα. Όταν, κάποια στιγμή, ένας κρατούμενος δραπετεύει και βιώνει τον κόσμο έξω από τη σπηλιά, μόνο τότε καταφέρνει και συνειδητοποιεί την αληθινή φύση της πραγματικότητας. Η αλληγορία του Πλάτωνα μας υπενθυμίζει ότι η εκπαίδευση δεν αφορά απλώς την παθητική πρόσληψη πληροφοριών (οι σκιές στον τοίχο), αλλά την ενεργό αναζήτηση της γνώσης και της αλήθειας. Η Τεχνητή Νοημοσύνη, αν και προσφέρει πολύτιμα εργαλεία για την πρόσβαση στις πληροφορίες, δεν πρέπει να εκλαμβάνεται ως η «απόλυτη πηγή» της αλήθειας. Οι μαθητές διατρέχουν τον κίνδυνο να αρχίσουν να βασίζονται στις συστάσεις της ΤΝ χωρίς να αξιολογούν κριτικά την εγκυρότητά τους ή να κατανοούν τις υποκείμενες παραδοχές τους - η φιλοσοφία του Πλάτωνα μάς ενθαρρύνει να καλλιεργήσουμε τον αλφαβητισμό της ΤΝ στους μαθητές, βοηθώντας τους να δουν πέρα από τις «σκιές» και να ασχοληθούν βαθύτερα με τη γνώση.

Τέλος, οι ηθικές αρετές του Αριστοτέλη, και ιδίως η έννοια της «φρόνησης» (πρακτική σοφία), μπορούν να προσφέρουν περαιτέρω καθοδήγηση για την ενσωμάτωση της ΤΝ στην εκπαίδευση. Για τον Αριστοτέλη, η εκπαίδευση δεν είχε να κάνει μόνο με την απόκτηση γνώσεων, αλλά και με την ανάπτυξη αρετών, καλών χαρακτηριστικών του χαρακτήρα που επιτρέπουν στα άτομα να κάνουν ορθές κρίσεις σε πολύπλοκες καταστάσεις. Η Τεχνητή Νοημοσύνη, με όλες τις δυνατότητές της για επεξεργασία και ανάλυση δεδομένων, δεν μπορεί να αναπαράγει το είδος της κρίσης με ευαισθησία στα συμφραζόμενα (context) που ο Αριστοτέλης περιέγραψε ως φρόνηση. Οι δάσκαλοι, επομένως, καλούνται να διαδραματίσουν έναν κρίσιμο ρόλο στην καθοδήγηση των μαθητών μέσα από ηθικά διλήμματα, βοηθώντας τους να αναπτύξουν την πρακτική σοφία που είναι απαραίτητη για την πλοήγηση στις πολυπλοκότητες της ζωής. Ενώ η Τεχνητή Νοημοσύνη μπορεί να παρέχει κάθε είδους πληροφορίες, είναι ο δάσκαλος (με την ευρεία έννοια της λέξης) που πρέπει να υποστηρίξει τους μαθητές να εφαρμόσουν αυτές τις πληροφορίες με ηθικά και δεοντολογικά υπεύθυνους τρόπους.

Ο εξελισσόμενος ρόλος των εκπαιδευτικών

Καθώς η Τεχνητή Νοημοσύνη φαίνεται να μπορεί να αναλάβει ή, έστω, να υποστηρίξει κάποια συνήθη εκπαιδευτικά καθήκοντα, όπως η βαθμολόγηση, η παροχή εκπαιδευτικού περιεχομένου, ακόμη και τμήματα της διδασκαλίας, ο ρόλος του εκπαιδευτικού εξελίσσεται. Αντί να αποτελούν την πρωταρχική πηγή γνώσης, οι εκπαιδευτικοί γίνονται όλο και περισσότερο καθοδηγητές των μαθητών στο μαθησιακό τους ταξίδι. Αυτή η μετατόπιση αντικατοπτρίζει το ρόλο του δασκάλου όπως τον οραματίστηκε ο Σωκράτης, ο οποίος έβλεπε τον εαυτό του όχι ως πηγή γνώσεων, αλλά ως «μαία» που βοηθά τους μαθητές να «γεννήσουν» τις δικές τους ιδέες. Η Τεχνητή Νοημοσύνη μπορεί να βοηθήσει τους εκπαιδευτικούς σε αυτή τη διαδικασία, παρέχοντας πληροφορίες σχετικά με τις επιδόσεις των μαθητών και εντοπίζοντας τους τομείς στους οποίους οι μαθητές μπορεί να χρειάζονται πρόσθετη υποστήριξη. Ωστόσο, ο εκπαιδευτικός είναι αυτός που πρέπει να εμπλέξει τους μαθητές στο είδος των ερωτήσεων και του διαλόγου που προάγει τη βαθιά κατανόηση και την κριτική σκέψη.

Αντίστοιχα, η έννοια του Αριστοτέλη για την Παιδεία αναφέρεται στην ολιστική ανάπτυξη του ατόμου: η εκπαίδευση, για τον Αριστοτέλη, ήταν κάτι περισσότερο από την απλή μετάδοση γνώσεων και περιελάμβανε τη διαμόρφωση του χαρακτήρα και των ηθικών αρετών του μαθητή. Καθώς η Τεχνητή Νοημοσύνη αναλαμβάνει περισσότερα καθήκοντα ρουτίνας, οι εκπαιδευτικοί απελευθερώνονται για να επικεντρωθούν σε αυτή την ευρύτερη πτυχή της εκπαίδευσης: μπορούν να αφιερώσουν περισσότερο χρόνο στην καλλιέργεια της δημιουργικότητας, της ηθικής συλλογιστικής και των κοινωνικο-συναισθηματικών δεξιοτήτων, τομείς στους οποίους η ανθρώπινη κρίση και ενσυναίσθηση είναι αναντικατάστατες. Με αυτόν τον τρόπο, η ΤΝ μπορεί να αποτελέσει ένα ισχυρό εργαλείο για την ενίσχυση του ρόλου του εκπαιδευτικού, επιτρέποντας στους εκπαιδευτικούς να επικεντρωθούν σε αυτό που κάνουν καλύτερα: την καλλιέργεια της πνευματικής και ηθικής ανάπτυξης των μαθητών τους.

Σε σχέση με τη μαθησιακή αυτονομία των μαθητών, μια από τις κεντρικές προκλήσεις της ενσωμάτωσης της ΤΝ στην εκπαίδευση είναι να διασφαλιστεί ότι την προωθεί, αντί να τη μειώνει. Ο Σωκράτης πίστευε ότι η εκπαίδευση πρέπει να δίνει στα άτομα τη δυνατότητα να σκέφτονται μόνα τους, να αμφισβητούν την εξουσία και να καταλήγουν στα δικά τους συμπεράσματα. Σε ένα εκπαιδευτικό περιβάλλον που κυριαρχείται από εργαλεία Τεχνητής Νοημοσύνης, διατρέχουμε τον κίνδυνο οι μαθητές να εξαρτώνται υπερβολικά από τις συστάσεις (recommendations) των αλγορίθμων, χάνοντας την ικανότητα για ανεξάρτητη σκέψη. Τα συστήματα Τεχνητής Νοημοσύνης που εξατομικεύουν τη μάθηση μπορούν, παραδόξως, να περιορίσουν την πνευματική εξερεύνηση, περιορίζοντας έτσι και το φάσμα του περιεχομένου στο οποίο εκτίθενται οι μαθητές, με βάση την προηγούμενη συμπεριφορά και τις επιδόσεις τους.

Για να προληφθεί αυτό το φαινόμενο, τα συστήματα Τεχνητής Νοημοσύνης πρέπει να σχεδιάζονται με τρόπους που ενθαρρύνουν την περιέργεια, την εξερεύνηση και την αυτό-κατευθυνόμενη μάθηση. Οι μαθητές θα πρέπει να ενθαρρύνονται να αμφισβητούν τις συστάσεις της ΤΝ, να αναζητούν εναλλακτικές προοπτικές και να αναλαμβάνουν νοητικά ρίσκα. Η έννοια της ευδαιμονίας (ανθρώπινη ευημερία) του Αριστοτέλη είναι σχετική με αυτήν τη σύσταση: για τον Αριστοτέλη, ο στόχος της εκπαίδευσης δεν ήταν απλώς η απόκτηση γνώσεων, αλλά η πραγμάτωση του πλήρους δυναμικού του ατόμου ως ανθρώπου. Η Τεχνητή Νοημοσύνη, ενώ είναι ικανή να παρέχει εξατομικευμένες μαθησιακές διαδρομές, θα πρέπει να χρησιμοποιείται με τρόπους που προωθούν τον ευρύτερο στόχο της ανθρώπινης ευημερίας, ενθαρρύνοντας τους μαθητές να αναπτύξουν στο έπακρο τις διανοητικές και ηθικές τους ικανότητες.

Η έμφαση του Σωκράτη στον διάλογο και την κριτική σκέψη, η αλληγορία του Πλάτωνα για την παρερμηνεία των φαινομένων με την πραγματικότητα και η εστίαση του Αριστοτέλη στην πρακτική σοφία και την αρετή προσφέρουν σημαντικά μαθήματα για το πώς πρέπει να αντιμετωπίσουμε τις ηθικές πολυπλοκότητες της ΤΝ στην εκπαίδευση. Καθώς διερευνούμε το πώς η ΤΝ μπορεί να αναδιαμορφώσει προς το καλύτερο το εκπαιδευτικό σύστημα, πρέπει πρώτα να διασφαλίσουμε ότι η ΤΝ χρησιμοποιείται για να ενισχύσει και όχι να αντικαταστήσει τα βασικά

ανθρώπινα στοιχεία της εκπαίδευσης - την προώθηση της αυτονομίας, της δημιουργικότητας, της ηθικής κρίσης και της κριτικής σκέψης. Τελικά, ο στόχος της ΤΝ στην εκπαίδευση δεν θα πρέπει να είναι να κάνει τη μάθηση απλά πιο αποτελεσματική, αλλά να την κάνει πιο ουσιαστική. Εξισορροπώντας τη δύναμη της ΤΝ με τις ηθικές αρχές που καθοδηγούν την εκπαίδευση εδώ και χιλιετίες, μπορούμε να διασφαλίσουμε ότι η ΤΝ θα χρησιμεύσει ως εργαλείο για την ανθρώπινη ευημερία, βοηθώντας τόσο τους μαθητές όσο και τους εκπαιδευτικούς να αξιοποιήσουν πλήρως τις δυνατότητές τους.

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Πρωτότυπες Εργασίες - Original Articles

AI Training and Copyright: Should Intellectual Property Law Allow Machines to Learn?

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Abstract

This article examines the intricate legal landscape surrounding the use of copyrighted materials in the development of artificial intelligence (AI). It explores the rise of AI and its reliance on data, emphasizing the importance of data availability for machine learning (ML) systems. The article analyzes current relevant legislation across the European Union, United States, and Japan, highlighting the legal ambiguities and constraints posed by IP rights, particularly copyright. It discusses possible new solutions, referencing the World Intellectual Property Organization's (WIPO) call for discussions on AI and IP policy. The conclusion stresses the need to balance the interests of AI developers and IP rights holders to promote technological advancement while safeguarding creativity and originality.

Keywords: Artificial Intelligence; copyright law; legal challenges; text and data mining; fair use.

Εκπαίδευση τεχνητής νοημοσύνης και πνευματική ιδιοκτησία: Θα πρέπει το δίκαιο πνευματικής ιδιοκτησίας να επιτρέπει στις μηχανές να μαθαίνουν;

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Περίληψη

Το άρθρο εξετάζει το σύνθετο νομικό τοπίο για τη χρήση υλικού τεχνητής νοημοσύνης (ΤΝ) που προστατεύεται από πνευματικά δικαιώματα. Διερευνά την ανάπτυξη της ΤΝ και τη σημασία της διαθεσιμότητας δεδομένων για τα συστήματα μηχανικής μάθησης (ML). Αναλύεται η ισχύουσα σχετική νομοθεσία στην Ευρωπαϊκή Ένωση, τις Ηνωμένες Πολιτείες και την Ιαπωνία, με έμφαση στις νομικές ασάφειες και τους περιορισμούς που θέτουν τα δικαιώματα πνευματικής ιδιοκτησίας. Διερευνώνται πιθανές νέες λύσεις, στο πνεύμα της πρόσκλησης του Παγκόσμιου Οργανισμού Διανοητικής Ιδιοκτησίας (WIPO) για την σχέση των προϊόντων ΤΝ και της πολιτικής για τη διανοητική ιδιοκτησία. Το συμπέρασμα τονίζει την ανάγκη εξισορρόπησης των συμφερόντων των προγραμματιστών ΤΝ και των κατόχων δικαιωμάτων διανοητικής ιδιοκτησίας για την προώθηση της τεχνολογικής προόδου με παράλληλη διασφάλιση της δημιουργικότητας και της πρωτοτυπίας.

Λέξεις κλειδιά: Τεχνητή Νοημοσύνη, δίκαιο πνευματικής ιδιοκτησίας, νομικά προβλήματα, εξόρυξη δεδομένων και κειμένου, δίκαιη χρήση.

1. Introduction to the problematic

The rise of high-performance Artificial Intelligence (AI), perceived as an ongoing revolution, has led several nations to develop AI strategies to capitalize on its significant benefits. Machine Learning (ML), a key subset of AI, drives this enthusiasm by enabling computers to autonomously improve their behavior and predictive capabilities, resulting in notable efficiency and advancement across various sectors.

Data, the digital representation of information, is essential for developing ML-based systems. These systems process large amounts of data to identify relationships and patterns, allowing algorithms to learn and make predictions or decisions based on new, unseen data. AI performance is directly proportional to the quantity and quality of data, making data availability crucial for AI development.

Generally, data is freely usable and transferable, not subject to ownership rights.[1] The EU has reinforced the importance of open data in the digital economy through several regulations,[2] aiming to make more data available, supporting the growth and innovation of data-driven technologies.

Despite the apparent accessibility of data, significant legal constraints, such as trade secrets, personal data rights, and state secrets, exist to safeguard other socially significant values. One of the most pronounced and litigation-prone restrictions in AI training is the protection of works provided by intellectual property (IP) rights, particularly copyright, which monopolizes the use of original creative works for a limited time to incentivize creativity and originality.

The presence of IP-protected works in AI training datasets introduces considerable legal ambiguity, posing challenges for AI developers in utilizing important publicly available data while risking numerous lawsuits, undermining the advancement of this technology and its social benefits.

Meanwhile, intellectual property owners also face obstacles. Despite holding, in principle, the rights to protect their creations, they often don't have the resources to effectively safeguard their intellectual property rights once their works have been processed into the algorithms along with large amounts of other data, making difficult to prove that their work was used in AI training.

Furthermore, as the accuracy of AI models heavily depends on data availability, copyright law can either enhance AI quality or disrupt it by causing biased decisions. While big tech companies can afford to produce their own data or pay for licenses, smaller AI entrepreneurs, fearing copyright infringement, often resort to less reliable sources such as “biased, low-friction data”, outdated public domain works, and potentially distorted data from Creative Commons (CC) licensed works from Wikipedia.[3] This reliance on "low quality" data jeopardizes the ethical integrity of AI systems, undermines essential social

[1] Property law is a closed system in civil law, which means that the law limits the number of real property rights. Since data is not legislated as an object of property, nor even unanimously qualified as “res”, there is no legal ownership of data.

[2] These include the Regulation (EU) 2018/1807 on the free flow of non-personal data, the Data Governance Act (Regulation (EU) 2022/868) to facilitate data sharing across sectors and EU countries, and the Directive (EU) 2019/1024 on open data and the re-use of public sector information.

[3] Levendowski A. How Copyright Law Can Fix Artificial Intelligence's Implicit Bias Problem, 93 Wash. L. Rev. 579 (2018). 602 - 619. Available at: https://digitalcommons.law.uw.edu/wlr/vol93/iss2/2

values, and affects the overall quality of AI tools, even for large companies.[4]

2. Current relevant legislation on IP protected data

Worldwide, there are few rules that provide legal certainty about the issues raised by the use of IP-protected works for AI training. It is therefore necessary to rely on the interpretation of established norms and case law in order to work out, on a case-by-case basis, the solution that a given legal system can provide to the matter.

2.1 European Union law

The European Parliament (EP) released a resolution on intellectual property rights for AI development (2020/2015(INI)), a non-binding guide. It recognizes the issues with tracing protected works used in AI, which hinders fair remuneration for authors, and suggests that auditable data records could improve protection for right-holders.

Making the European Union (EU) the world leader in AI technologies is referred to as a goal, requiring an effective intellectual property system suited for the digital age, removing legal barriers, and unlocking AI's potential in the data economy. It stresses the importance of balanced IP rights protection to ensure legal certainty, build trust, and encourage investment, while also protecting human creators and adhering to ethical principles.

Finally, The EP emphasizes that the lawful use of copyrighted works and data in AI must be assessed under existing copyright limitations and exceptions, such as the text and data mining exception in the Directive on copyright in the Digital Single Market.

2.1.1 Copyright and database sui generis protection

Copyright protects the "rights of the author in their literary and artistic work"[5] rather than ownership of the work. In Europe, this protection is automatic, requiring no registration, following the Berne Convention.

Originality is traditionally a condition to the establishment of copyright among continental states, following the French doctrine of‘ Droit d’Auteur’. The EU's Software, Term, and Database Directives describe it as "the author’s own intellectual creation,"[6] a concept extended by the Court of Justice of the European Union (CJEU) to all subject matters in the Infopaq decision.[7] This notion reflects the author's personality, interpreted by the CJEU as the ability to make free and creative choices[8], imprinting the work with a personal touch.[9]

According to CJEU case law, the measure of originality required for the work to be protected can be very modest. In Infopaq I, for instance, the Court of Justice stated that while individual words are not protectable, their combination and selection can be done in a way that express the author’s creativity in an original manner, con-

[4] The inclusion of data derived from additional copyrighted works increases the overall size of the dataset, which can reduce the relative importance of low-quality, free-use data.

[5] Art. 1 of the Berne Convention for the Protection of Literary and Artistic Works (as amended on September 28, 1979).

[6] See respectively article 1/3 of the Software Directive, article 3/1 of the Database Directive and article 6 of the Term of Protection Directive.

[7] Case C-05/08 Infopaq International, ECLI:EU:C:2009:465.

[8] Case C-604/10 Football Dataco, at 39.

[9] Case C-145/10 Painer, ECLI:EU:C:2011:798.

cluding that even eleven consecutive words can potentially express the author's own intellectual creation.[10]

In addition to copyright[11], the EU recognizes in a pioneering way a legal protection of databases, defined as "a collection of independent works, data or other materials arranged in a systematic or methodical way and individually accessible by electronic or other means" (art. 1º/2 Database Directive), a concept that embody both the protected and non-protected works that constitute the database.

The Directive 96/9/EC of the European Parliament and of the Council of 11 March 1996 (Database Directive) established a dual protection regime, a copyright, not for the content of the database, but for the arrangement or selection of the content that "constitute the author's own intellectual creation" (art. 3º) and a sui generis right for the maker of the database that limit the extraction of the database's content. (art. 7º)

The sui generis right for the database maker is a related right of copyright created to protect the investment deployed in the obtaining, verification or presentation of the contents by prohibiting the extraction and reutilization of the whole or of a substantial part of the contents of that database, while extracting and reutilizing insubstantial parts of it that results from normal exploitation of the database is permitted (art. 8º). According to the CJEU jurisprudence, the extraction and reutilization of the database content will be prohibited only when such actions risk depreciating the protected investment, reducing considerably the scope of database content protection.[12]

Regarding that, in Europe, there is no requirement for registration of copyrighted material, the low originality criteria for a production to be considered protected and even the limitation of the use of non-protected work within databases, the possibility of IP-protected work to integrate the data used in AI training is enormous. Consequently, the development of ML models would be constantly under the threat of illegality when if no exceptions apply.

2.1.2 Text and data mining exception

The Directive (EU) 2019/790 of the European Parliament and of the Council of 17 April 2019 on copyright and related rights in the Digital Single Market adopted an exception to the prohibition of unauthorized reproductions and extractions of protected works for the purposes of text and data mining (TDM).

TDM, defined as an "automated analytical technique aimed at analyzing text and data in digital form in order to generate information which includes but is not limited to patterns, trends and correlations," represents most of what AI developers do when training AI systems and could facilitate the use of IP-protected data, but the scope of the exceptions is limited.

This permitted use of protected work was originally created for research purposes. The European legislation, recognizing the importance of the exploitation of all kinds of data to gain knowledge and promote innovation, provided a mandatory exception to the exclusive right of reproduction and to the right to prevent extrac-

[10] ECJ, Case C-5/08 Infopaq International, para. 48.

[11] Directive 2001/29/EC of the European Parliament and of the Council of 22 May 2001 on the harmonization of certain aspects of copyright and related rights in the information society.

[12] Sousa e Silva N. 'Inteligência Artificial e Propriedade Intelectual: Está tudo bem?' I Congresso de Inteligência Artificial e Direito, Edições Almedina (2023), 201-220.

tion from a database "by research organizations and cultural heritage institutions in order to carry out, for the purposes of scientific research, text and data mining of works or other subject matter to which they have lawful access". (art. 3º/1)

Stakeholders that have different purposes than exclusively research, including commercial, are as well beneficiaries of the exception to encourage innovation also in the private sector. However, there is one extra requirement, the right-holders of the IP-protected work can't have expressly reserve the rights to make reproductions and extractions for text and data mining (art. 4º/3). It represents a presumed license (opt-out) applicable to IP-protected works that have to be expressively denied by the right-holder to prevent or monetize the use of his/her work by TDM.

Despite the directive's aim to promote innovation through lawful data analysis essential for data-driven technologies, the opt-out provision for text and data mining (TDM) has led to a general contractual ban on TDM in the terms and conditions of much publicly available content. This ban is often reinforced by technical measures that prevent crawling and indexing necessary for TDM.[13] Consequently, the TDM exception has been effectively obstructed when right-holders opt-out, making the prohibition of TDM a standard practice in terms and conditions.

2.1.3 EU AI Act

The European regulation on AI (AI Act), a pioneering piece of legislation on AI regulation, is currently in its final stages of implementation. Although this legal document does not affect the enforcement of copyright rules as provided for under Union law, it embodies important statements and rules regarding the use of IP-protected works in AI development.

Following the mentioned resolution of the European Parliament, recital 105 of the AI Act confirms the EP position that the use of copyright, and related rights, protected content requires the authorization of the rightsholder concerned unless relevant copyright exceptions and limitations apply. Article 53/1/c of the regulation goes further regarding the application of Directive (EU) 2019/790 in AI training. It implements the obligation for providers of general-purpose AI models[14] to put in place a policy to identify and comply with the expressed reservations of copyrights and related rights (the opt-out). All the providers should comply with this obligation, regardless of the jurisdiction in which the copyright-relevant acts used in the training of those general-purpose AI models take place (Recital 106).

The AI Act establishes another important provision about the content used to power general-purpose AI models, the obligation for its providers to draw up and make public available "a sufficiently detailed summary about the content used for training of the general-purpose AI model, according to a template provided by the AI Office" (Art. 53/1/d). The summary have to take into account the need to protect trade secrets

[13] Ducato R, Strowel A. "Limitations to Text and Data Mining and Consumer Empowerment Making the Case for a Right to "Machine Legibility". CRIDES Working Paper Series, 31 October 2018.

[14]" AI model, including where such an AI model is trained with a large amount of data using self-supervision at scale, that displays significant generality and is capable of competently performing a wide range of distinct tasks regardless of the way the model is placed on the market and that can be integrated into a variety of downstream systems or applications, except AI models that are used for research, development or prototyping activities before they are released on the market". (Article 3/63 of the AI Act).

and confidential business information and be generally comprehensive in its scope instead of technically detailed to facilitate parties with legitimate interests, including copyright holders, to exercise and enforce their rights under Union law (Recital 107).[15]

Compliance with the obligations applicable to the providers of general-purpose AI models should be proportionate to the type and size of model provider, excluding the need for compliance for persons who develop or use models for non-professional or scientific research purposes, and should allow simplified ways of compliance for SMEs, including start-ups, that should not represent an excessive cost and not discourage the use of such models (Recital 109).

It is important to have in mind that the obligations emerged from the EU AI Act are not restricted to the AI models developed within the European Union's territory. This legislation has a territorial scope extended to all providers that place on the market both AI systems or general-purpose AI models in the Union and if the output produced by the AI system is used in the Union, irrespective of whether those providers are established or located within the Union or in a third country (art. 2/1/a and art. 2/1/c). Such significant extraterritorial effect obliges all the AI developers and providers interested in the expressive European market to comply with the requirements of the AI Act, transforming this activity in a potentially worldwide way.

2.2 United States legislation and case law

Copyright in the United States, unlike the French 'Droit d'Auteur,' aims to promote artistic progress for public intellectual enrichment by allowing authors to benefit from their creative labor. This utilitarian approach is enshrined in the US Constitution, which empowers Congress to secure exclusive rights for authors and inventors for limited times to promote progress in science and useful arts.[16] To guarantee that the established objective of copyright isn't disturbed by its right holders, three judicial doctrines have been established: copyright protects the form of expression, not ideas; facts are not protected by copyright regardless of discovery effort; and the fair use doctrine, which legitimizes secondary creativity.[17]

2.2.1 Fair use doctrine

The fair use doctrine is an exception from copyright formalized by Title 17 of the US Code §107, allowing the use of copyrighted materials without the owner's consent. The main idea is that the copy serves a different function from the original work and doesn't create a substitution, also known as transformative use. In the words of Judge Pierre Leval, who articulated the concept:

"The use must be productive and must employ the quoted matter in a different manner or for a different purpose from the original.... If... the secondary use adds value to the original -if the quoted matter is used as raw material, transformed in the creation of new information, new aesthetics, new insights and understandings- this is the very type of activity that the fair use doctrine intends to protect for the enrichment of society."[18]

[15] The norms of Articles 53/1/c and 53/1/d are also applied to general-purpose AI models under free and open source license. (Recital 104 and Art. 53/2 of the AI Act).

[16] Constitution of the United States. art. I, § 8, cl. 8.

[17] Leval PN. Commentary, Toward a Fair Use Standard,103 HARV. L.REV (1990). 1105, 1111.

[18] Ibidem.

Fair use is a mixed question of law and fact, which means that the finding of whether something constitutes fair use is case-specific considering (1) the purpose and character of the use, including whether such use is of a commercial nature or is for nonprofit educational purposes; (2) the nature of the copyrighted work; (3) the amount and substantiality of the portion used in relation to the copyrighted work as a whole; and (4) the effect of the use upon the potential market for or value of the copyrighted work.[19]

In Authors Guild, Inc. v. Google, Inc., in 2015, the court decided that copy a work to extract information not protected by copyright is lawful according to fair use. This understating could cover also Machine Learning uses, where the data extracted from copyrighted works for pattern analysis aren't explicitly covered by copyright rules.

2.2.2 Case Law

The advent of generative AI systems based on Machine Learning promoted a series of lawsuits concerning the alleged use of copyrighted work to train AI systems without the authorization or license of the right holder, the plaintiffs claim that such use is an infringement of the monopoly right of exploring their work.

In Getty Images v. Stability AI, filed in February 2023 in Delaware, Getty Images alleged that Stability AI used over 12 million of its images to train Stable Diffusion, violating Getty's terms of use. The court rejected the defendants ' motion to dismiss in January 2024. Another lawsuit involves visual artists Sarah Andersen, Kelly McKernan, and Karla Ortiz, who filed a class action in January 2023 in California against Stability AI, Midjourney, and DeviantArt, claiming these companies used their copyrighted works to train various AI models, resulting in outputs that are "indistinguishable" from theirs. In October 2024, the court allowed Andersen's claims regarding her registered works to proceed but dismissed other claims. OpenAI also faces a lawsuit from authors Paul Tremblay, Sarah Silverman, Christopher Golden, and Richard Kadrey, who allege that their copyrighted books were used to train ChatGPT. The court dismissed most claims against OpenAI, except for direct copyright infringement, but no merits decision had been taken.

In Thomson Reuters v. ROSS, the issue of fair use in AI training was addressed for the first time. ROSS was accused of using Thomson Reuters 'proprietary information from the Westlaw platform to enhance its AI-powered legal platform, leading to claims of copyright infringement and tortious interference with contract. The court denied ROSS's motions to dismiss and for summary judgment, emphasizing that the plaintiffs 'claims warranted a jury trial. The court highlighted the four factors of fair use under Title 17 of the US Code §107: whether ROSS's AI merely analyzed language patterns or directly replicated copyrighted content, the nature of the copyrighted work and its protection, the extent and necessity of copying for transformation, and the potential market impact and public benefit, all of which required a jury's assessment.

Finally, In December 2023, The New York Times filed a lawsuit against OpenAI and its major financial backer, Microsoft, alleging unauthorized use of millions of its articles to train chatbots. The Times claims this constitutes "free-riding" on its significant investment in journalism and creating a substitute for the newspaper, seeking "billions of dollars in statutory and actual damages." Additionally, the lawsuit demands the deletion of all chatbot models and training data containing copyrighted material from The Times. This case is significant as The Times has a history of defending its journalistic expression through litigation, potentially resulting in substantial monetary penalties under the statutory damages clause of the Copyright Act and the destruction of GPT-based products if The Times wins, it could also establish new fair use prece-

[19] Copyright Law of the United States and Related Laws Contained in Title 17 of the United States Code, pp. 20.

dents, as the defense is based on Section 107 of the Copyright Act.

2.2.3 Proposed bill for the "Generative AI Copyright Disclosure Act of 2024"

Many cases struggle with the lack of evidence regarding the use of copyrighted material for AI training, as AI outputs are influenced by datasets but typically do not reproduce the works entirely, leaving copyright owners to base lawsuits on detected similarities in AI outputs as indirect proof. To address this, Article 53/1/d of the EU AI Act requires AI developers to disclose all training data in a clear summary without compromising trade secrets or confidential commercial information.

In the United States, a similar bill for the "Generative AI Copyright Disclosure Act of 2024," was introduced by Congressman Adam Schiff. This proposed legislation requires a detailed summary of all copyrighted works used in generative AI systems, with a civil penalty of at least $5,000 for non-compliance. Unlike the EU provision, this bill has a retroactive effect, giving companies with existing AI systems 30 days to submit the summary, and new systems must comply 30 days before public release. Supported by numerous entertainment industry organizations and unions, this legislation would enhance transparency in AI development but leaves the determination of fair use applicability to the courts.

2.3 Japanese legislation and data analyses exception

The Japanese legal system has one of the most permissive legislations worldwide regarding the use of copyrighted training data for AI development. An amendment to the Copyright Act of Japan in 2018 introduced Article 30-4, which establishes an exception to copyright protection applicable to AI training. This allows providers to conduct machine learning relatively free of legal issues.

According to Article 30-4, the use of copyrighted material without the permission of the copyright holder is permitted to the necessary extent if the purpose is not for oneself or others to enjoy the thoughts and sentiments expressed in the work. The provision includes examples where the purpose is not human enjoyment, such as "information analysis," listed in item 2. AI training typically falls within this category since it uses the work as data to extract information rather than to create enjoyment from the ideas or feelings expressed in the work.

However, this exception does not apply when the use creates new works that evoke essential characteristics or the creative expression of the original.[20] Additionally, the provision is not applicable if the action unreasonably prejudices the interests of the copyright owner, determined on a case-by-case basis by considering if it conflicts with the market of the copyright holder's works or prejudices potential future markets.[21]

The Japanese Copyright Act does not clarify if using data from a website as training data for algorithms is permissible if the website's Terms of Use prohibit such use. This creates legal uncertainty regarding the acceptance of data use in violation of terms of use or contracts. Another concern is the jurisdiction of Japanese law, particularly in cases where AI developers need to determine the legality of their actions. Generally, copyright infringement is regulated by the laws of the country where the infringement occurred. The location of the server providing the AI model is crucial in determining jurisdiction, potentially affecting the application of Japan's copyright exception when foreign service providers use training data on servers located abroad, even

[20] Fukuoka, Shinnosuke; Murata, Tomonobu; Mizuguchi, Atsuki. Legal Issues in Generative AI under Japanese Law - Copyright. Robotics / Artificial Intelligence Newsletter, 2023

[21] Basic ideas on flexible rights limitation provisions in response to the development of digitization and networking (related to Articles 30-4, 47-4 and 47-5 of the Japanese Copyright Act), Japan Copyright Office.

if the users are in Japan. Conversely, service providers developing AI in Japan with users abroad would presumably be subject to Article 30-4 of Japan's Copyright Act.

3. Possible new solutions

Globally, the issues arising from the impact of AI on IP remain unsettled, leading the World Intellectual Property Organization (WIPO) to release a 2019 document addressing these concerns.[22] Section 13 focuses on copyright issues related to AI training data that may include creative works subject to copyright. The document outlines key issues for discussion to form a shared understanding but does not provide conclusions or recommendations. WIPO's IP global forum aims to clarify existing law interpretations, guide stakeholders, and facilitate international norms. Key inquiries include whether using copyrighted data without authorization for machine learning constitutes infringement, and if explicit exceptions should be made under copyright law.

In addition to the different existing jurisdictions that may present a solution to this emerging issue, different approaches have been supported by experts in recently published doctrine. Among them are the creation of a more permissive TDM exception, the establishment of an online clearinghouse for ML training and the interpretation of the American fair use doctrine taking into account the fair learning principle.[23]

3.1 Broader Text and Data Mining exception

The Joint Comment to WIPO on Copyright and AI, endorsed by 16 members of the Global Expert Network on Copyright User Rights, aims to stimulate discussion on the implications of freedom to use training corpora for commercial or scientific purposes, without presenting an ultimate solution. It distinguishes between two processes involving protected works and text and data mining (TDM) for AI training, questioning if existing law should allow these processes.

The first TDM-relevant activity involves applying computational processes to copyrighted works to derive data, such as conducting internet searches or querying databases like Google Books. The authors argue that although this involves using data derived from copyrighted works without authorization, it often does not constitute a copyright infringement due to the fact/expression dichotomy in law. However, computational processes may require reproducing and storing copyrighted works, raising whether creating a database to be mined necessitates a copyright exception.

R. Ducato and A. Strowel assert that when reproductions are made for search and TDM, the work is not used as a work but merely as a tool to derive information, without public enjoyment of the expressive features. They argue that TDM should not be considered illicit, as it does not meet the 'use of the work as a work' condition for

[22] *Cfr*. WIPO, WIPO Conversation on Intellectual Property (IP) and Artificial Intelligence (Al), Draft Issues Paper on Intellectual Property and Artificial Intelligence, Second Session, WIPO Secretariat, available at: https://www.wipo.int/edocs/mdocs/mdocs/en/wipo_ip_ai_2_ge_20/wipo_ip_ai_2_ge_20_1.pdf (accessed on 23/04/2024).

[23] Kop M. Machine Learning & EU Data Sharing Practices (March 3, 2020). Stanford - Vienna Transatlantic Technology Law Forum, Transatlantic Antitrust and IPR Developments, Stanford University, Issue No. 1/2020, Available at: https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3409712

copyright infringement.[24] The Joint Comment also highlights the potential negative impact on TDM research, machine learning, and AI development if these processes are deemed copyright infringements without an exception. Examples are the equity and ethical issues, such as transparency, accountability and algorithmic discrimination;[25] and the impacts of a globally fragmented legal system to the extent different national laws took different approaches to answering.

The text suggests that WIPO should also evaluate the purpose limitations of research exceptions, especially those limited to 'non-commercial' research,[26] considering their impact on public-private partnerships and socially beneficial commercial TDM products like internet search and language translation. Ducato and Strowel critique the narrow scope of the European TDM exception, emphasizing that TDM should promote research innovation for both commercial and non-commercial purposes, as the boundary between these types of research is often blurred.[27]

3.2 Online Clearinghouse for machine learning training

Given the wide range of works and owners involved in machine learning training sets, licensing each individual piece of copyrighted material is impractical and would likely obstruct, rather than facilitate, the use of such data.[28] The WIPO Conversation on IP and AI explores alternatives for dealing with the unauthorized use of copyrighted data, including the feasibility of a collective rights society similar to a "one-stop shop" with a compulsory licensing system. This system would allow for the commercial and scientific use of data, while ensuring that rightsholders are compensated, thus reconciling the flow of data with the interests of creators who contribute to the development of AI.

However, implementing such a system poses significant challenges. The large volume of works and the diversity of their owners complicate licensing agreements, raising questions of jurisdictional boundaries and the regulatory basis for licensing non-expressive uses that do not compete in the original market. Questions also arise about who should benefit from such a system - authors, publishers or Collective Management Organizations - and concerns about over-licensing, particularly when non-expressive or functional elements of copyrighted works are used for data mining and machine learning purposes. These complexities highlight the need for careful analysis and possibly new legal frameworks to effectively manage licensing in the context of AI development.

3.3 Fair Learning

Obtaining legal protection through fair use of copyrighted works for AI training involves navigating a complex and unpredictable framework defined by four fact-specific factors. Professor Larry Lessig famously characterized fair use as simply the right to hire a lawyer due to its uncertainty. For AI training datasets, several fair use factors often weigh against its application, such as the wholesale copying of entire works without alteration, directly impacting the third statutory factor that assesses the amount of the work used.

Moreover, AI's capability to replicate outputs of creative professionals raises concerns about its competitive implications, potentially influencing how courts view the substitutive nature of a permissive fair use doctrine. The sheer volume of works involved further complicates matters, increasing the risk of litigation from numerous copyright holders, discouraging many AI companies from relying on fair use as a legal defense.

[24] *See* Ducato and Strowel, *supra* note 13.
[25] *See* Levendowski, *supra* note 3.
[26] Article 3/1 of the Directive (EU) 2019/790 of the European Parliament and of the Council of 17 April 2019.
[27] *See* also Ducato and Strowel, *supra* note 13.
[28] *See* Lemley and Casey, *infra* note 29.

In response to these challenges, Mark Lemley and Bryan Casey propose integrating a principle they term "fair learning" into the fair use analysis of AI training data.[29] The principle posits that uses aiming not to obtain or integrate copyrightable elements of a work but to access, learn, and utilize its unprotectable aspects should be deemed presumptively fair under the first fair use factor,[30] which assesses the purpose and character of the use. It suggests that only if such use significantly disrupts the plaintiff's core market should the fourth fair use factor,[31] outweigh a determination of fair learning under the first factor. This approach seeks to provide a structured framework that recognizes the transformative nature of AI applications while carefully balancing the rights of copyright holders.

The fair learning principle acknowledges that not all uses of copyrighted material by ML systems can be considered fair. Some AI applications specifically seek to incorporate the expressive elements of works, which are protected by copyright, into their training sets. This approach poses a risk of significant substitutive competition with the original work, potentially impacting its market. However, fair learning holds that learning from copyrighted material should generally be allowed, similar to the way people learn from cultural pieces for personal enrichment. Most ML systems aim to extract public domain factual or structural information from works, using this knowledge for practical applications rather than for consuming the protected expression itself. Recognizing this distinction as fair learning helps ensure that ML development can proceed without unjustified legal constraints.

The adoption of fair learning as a lawful purpose under the first factor would favor the idea that fair use is not constrained to the use that are transformative or that have no market consequence,[32] but rather applies when they serve valuable social purpose,[33] opening the way to a more pluralistic vision of fair use.

4. Conclusion

Considering both the objectives of the utilitarian American copyright law and the creativity protective droit d'auteur, the use of copyrighted (and neighboring rights protected) materials to collect information should not be considered illegitimate, since the technological process does not aim to use the work as a creative expression, but as a source of quality data necessary for the proper functioning of the machine. Furthermore, its mere use in AI training does not discourage the production of creative content, but instead stimulates it through new tools and exciting potential.

The real legitimate concern for authors of works used in the development of AI models is the possible use of these systems to generate content that is similar to their original work in a way that replaces or limits its market, which would also be considered an infringement of the author's copyright if it were carried out by a human without the use of tools based on AI.

[29] Lemley MA, Casey B. Fair Learning (January 30, 2020). Available at: https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3528447.

[30] Ideas, facts, functions, methods, and stock literary are not protectable by copyright law.

[31] For example, withdrawing an entire training database directly affects the market, as its value lies in its use for ML, unlike the value of any individual copyrighted work.

[32] The fair use doctrine emphasizes transforming copyrighted works, but machine learning systems typically don't transform the databases they train on, often using them entirely for commercial purposes.

[33] *See* Levendowski, *supra* note 3.

One possible way to balance the legitimate interests involved in using IP-protected works for training AI could be, firstly, implementing a text and data mining exception for any use (both research and commercial), as seen in Japanese law and intended by European law.[34] Secondly, it could involve a policy that ensures transparency for the author, similar to European and American legislative initiatives,[35] while also protecting the creativity inherent in the works used for AI training.

Copyright, due to the central doctrine of "idea-expression dichotomy," does not support prohibiting the use of a creative work in order to remove relevant information that serves to the development of AI. Establishing a general exception for TDM with no opt-outs would provide the legal certainty that this promising technology needs, while also avoiding the risks of bias and monopolization that restricting the use of protected works potentially causes.[36]

Likewise, it is pertinent to protect the legitimate interest of authors by requiring the disclosure of works used in AI training, as it permits audibility and empowers authors to demonstrate when their work is unfairly prejudiced. Additionally, implementing a specific regime to prevent AI outputs from closely resembling original works is essential to protect authors from losing market share. This result can be pursued both by regulating the technology so that it does not allow such plagiarism to take place,[37] and by stipulating an appropriate sanction for users who, despite technological impediments, have used a usurped creative expression to limit or replace the market for the original work used to train the AI.

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[34] The EU's aim was to promote innovation by allowing lawful data analysis, which is essential for the development of data-driven technologies. However, the opt-out approach for TDM has resulted in generalized contractual prohibitions of TDM in the terms and conditions of publicly available content.

[35] Successively, the EU AI Act and the Bill for the Generative AI Copyright Disclosure Act.

[36] *See* Levendowski, *supra* note 3.

[37] This provision could be enforced by another AI-powered system that monitors the works used in the audited AI's training dataset through legally required summaries. This monitoring AI would compare the audited system's results with copyrighted works to detect infringements, though specific criteria for detection must be developed. Additionally, the monitoring AI could define the permissible purposes for using the AI output.

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Πρωτότυπη Εργασία

Navigating Precision Medicine Within European Law: Ethical Considerations and Legal Challenges

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Abstract

Precision medicine, characterized by personalized treatment strategies based on extensive patient-specific data, has gained prominence in recent years. This paradigm shift from the traditional one-size-fits-all approach aims to optimize healthcare outcomes by integrating genomic, clinical, and lifestyle information. While precision medicine's transformative impact in fields like oncology and pharmacogenomics is evident, regulatory frameworks, including GDPR, Clinical trials regulation, IVD regulation, and the recently effective Health Technology Assessment Regulation (HTAR) from January 2025, are scrutinized for their contributions and identified gaps. Despite significant progress, challenges persist, including issues related to informed consent, companion diagnostics, direct-to-consumer genetic tests, intellectual property rights, and diverse healthcare policies across the EU. The lack of global harmonization adds complexity to regulatory environments. The conclusions stress the dynamic nature of precision medicine, proposing proactive measures such as the establishment of multidisciplinary committees within the EU to adapt swiftly to emerging advancements and ensure seamless integration into healthcare systems. This symbiotic relationship between precision medicine and European law reflects a commitment to creating an environment where cutting-edge medical technologies can thrive, contributing to a healthier and more resilient population through ongoing efforts to refine legal frameworks.

Keywords: precision medicine, European legal frameworks, ethical considerations, healthcare policies.

Ιατρική Ακριβείας στο Πλαίσιο του Ευρωπαϊκού Δικαίου: Ηθικές Παρατηρήσεις και Νομικές Προκλήσεις

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Περίληψη

Η ιατρική ακριβείας, που χαρακτηρίζεται από εξατομικευμένες στρατηγικές θεραπείας βασισμένες σε εξειδικευμένα δεδομένα που αφορούν συγκεκριμένο ασθενή, έχει κερδίσει έδαφος τα τελευταία χρόνια. Αυτή η αλλαγή από την παραδοσιακή προσέγγιση "one-size-fits-all" στοχεύει στη βελτιστοποίηση της υγειονομικής περίθαλψης ενσωματώνοντας πληροφορίες σχετικά με το γονιδίωμα του ασθενούς, του τρόπου ζωής και κλινικά αποτελέσματα. Ενώ ο αντίκτυπος της ακριβούς ιατρικής σε τομείς όπως η ογκολογία και η φαρμακογενετική είναι εμφανής, τα ρυθμιστικά πλαίσια, συμπεριλαμβανομένων του ΓΚΠΔ (GDPR), του Κανονισμού Κλινικών Δοκιμών, του Κανονισμού για τα in vitro διαγνωστικά και του πρόσφατα ισχύοντος(Ιανουάριο 2025) Κανονισμού Αξιολόγησης Τεχνολογίας Υγείας (HTAR), υπόκεινται σε λεπτομερή εξέταση για τις συνεισφορές και τα κενά που εντοπίζονται. Παρά την σημαντική πρόοδο, εξακολουθούν να υφίστανται προκλήσεις, όπως ζητήματα που σχετίζονται με την συναίνεση, τα συνοδευτικά διαγνωστικά τεστ, τα γενετικά τεστ, τα δικαιώματα πνευματικής ιδιοκτησίας και τις ποικίλες πολιτικές υγειονομικής περίθαλψης σε όλη την ΕΕ. Η έλλειψη παγκόσμιας εναρμόνισης προσθέτει πολυπλοκότητα στα ρυθμιστικά περιβάλλοντα. Τα συμπεράσματα τονίζουν τη δυναμική φύση της ιατρικής ακριβείας, προτείνοντας προληπτικά μέτρα όπως η ίδρυση διεπιστημονικών επιτροπών εντός της ΕΕ για την ταχεία προσαρμογή στις νέες εξελίξεις και τη διασφάλιση της απρόσκοπτης ενσωμάτωσης στα συστήματα υγειονομικής περίθαλψης. Αυτή η συμβιωτική σχέση μεταξύ ιατρικής ακριβείας και ευρωπαϊκού δικαίου αντανακλά τη δέσμευση για τη δημιουργία ενός περιβάλλοντος όπου οι προηγμένες ιατρικές τεχνολογίες μπορούν να ευδοκιμήσουν, συμβάλλοντας σε έναν πιο υγιή πληθυσμό μέσω συνεχών προσπαθειών για τη βελτίωση των νομικών πλαισίων.

Keywords: ιατρική ακριβείας, ευρωπαϊκά νομικά πλαίσια, ηθικές προκλήσεις, πολιτικές υγειονομικής περίθαλψης.

1. Introduction

Precision medicine (PM) is an innovative approach to treatment and prevention that utilizes large-scale data, including a patient's unique genome, environment, lifestyle, and biomarker information. Gaining popularity due to scientific advancements and political support, PM emphasizes a personalized approach within the doctor-patient dynamic. Unlike traditional personalized medicine, which simply tailored care to individual patients, PM leverages extensive individual-specific data to offer deeper insights beyond observable clinical signs and symptoms (1).

PM integrates genomics, proteomics, and metabolomics to analyze biomarkers in large sample groups or specific diseases. This approach combines standardization with individualization, aiming to fully understand a patient's genetic information to predict diseases and provide optimal prevention, diagnosis, and therapy. This enables healthcare providers to select appropriate medications, determine optimal dosages, and minimize side effects. The overarching goal of PM is to reduce major diseases' incidence, lower morbidity and mortality rates, enhance medical care quality through technological advancements, and ultimately improve human health (2).

The completion of the Human Genome Project (HGP) in 2001 revolutionized medicine by enhancing the understanding of genetics. Subsequent projects, like the International HapMap Project and the 1000 Genomes Project, continue to influence clinical practice, making DNA sequencing and big data analysis crucial for PM (3).

PM has shown significant potential in oncology and pharmacogenomics. In oncology, PM enables tailored treatment strategies based on the genetic and molecular characteristics of individual cancer patients, improving treatment effectiveness and patient outcomes. For instance, sequencing BRCA1 and BRCA2 genes helps assess breast and ovarian cancer risks. Trastuzumab, a monoclonal antibody, is prescribed for metastatic breast cancer patients with high HER2 gene expression (4).

As PM advances, examining the legal and ethical frameworks surrounding it is crucial, particularly within the European context. Large-scale databases, new patient classification methods, and advanced data analysis tools necessitate robust ethical, legal, and social frameworks. These frameworks must protect patients while fostering innovation and trust between patients and healthcare providers (5,6).

This article explores the intersection of PM and European law, addressing legal challenges, regulatory gaps, and ethical considerations. It aims to analyze European legal frameworks related to data protection, privacy, intellectual property, research ethics, and healthcare regulations, proposing recommendations to strengthen the regulatory framework.

2. Precision Medicine in Clinical Practice

2.1 Precision Medicine in Oncology and Pharmacogenomics

In the domain of oncology and pharmacogenomics, PM represents a revolutionary approach. It harnesses genomic and proteomic profiling, along with other biological traits of cancer, to pinpoint actionable mutations and biomarkers, aligning treatment strategies with these unique biological abnormalities. This all-encompassing concept spans molecular diagnostics, molecularly targeted therapies, next-generation sequencing (NGS), and immunotherapies. It originated with the discovery of single-gene mutations in certain cancer patient subsets, leading to the development of molecularly targeted therapies tailored to these genetic mutations. As PM has evolved, it now includes the analysis of multiple genes and comprehensive cancer cell DNA sequencing, in addition to immunotherapies designed to detect and combat cancer cells by modulating the immune system. Distinguishing itself from traditional approaches, PM tailors therapy to an individual's genomic mutations or biomarkers, promising enhanced treatment efficacy and reduced toxicity, thus signaling a transformative era in oncology and pharmacogenomics (7). PM in the context of cancer strives to deliver the appropriate

treatment, in terms of medication and dosage, to the specific patient at the optimal moment (8).

Pharmacogenomics (PGx) is the exploration of how genetic variations in genes responsible for drug metabolism and transport, impact drug levels at the intended site (pharmacokinetics), as well as in genes related to drug target proteins like receptors, enzymes, and intracellular signaling proteins, influence an individual's responsiveness to a drug (pharmacodynamics) (8).

Genetic testing and risk assessment constitute pivotal pillars in the realm of PM. Genetic testing includes the examination of an individual's genetic makeup to uncover specific genetic variants, mutations, or alterations associated with disease susceptibility or risk. This genetic information serves as a cornerstone for early disease detection, including rare genetic disorders. Moreover, this information plays an indispensable role in targeted therapies, based on an individual's genetic profile. Therefore, the possible applications of genetic testing encompass furnishing crucial information for patient or family care, diminishing the risk of illness or death, and offering insights for reproductive decision-making (9). These assessments provide healthcare professionals with invaluable insights into a patient's genetic predisposition, especially when it comes to rare diseases caused by single gene alterations.

Pharmacogenetic testing has also demonstrated efficacy in both reactive and preemptive settings, particularly concerning treatment response. Numerous studies highlight the cost-effectiveness of testing, which is significantly lower than addressing potentially life-threatening severe ADRs. To ensure the successful integration of pharmacogenetic testing, it is imperative to establish standardized implementation processes. Pharmacogenetic testing is on track to become a fundamental pillar in the realm of PM (10).

2.2. Role of Biomarkers in Diagnosis, Prognosis and Drug Response Prediction

A biomarker is a biological measurement that can be used as a substitute for, and ideally predict, a clinically significant outcome or a middle-stage result that may be harder to directly observe. Using clinical biomarkers is more convenient and cost-effective than directly measuring the final clinical outcome, and these biomarkers are typically assessed over a shorter period (11).

Biomarkers primarily serve as tools for key purposes such as screening, characterizing diseases, ruling out, diagnosing, staging, monitoring diseases, and offering prognosis information(11). An additional significant utility of biomarkers lies in their capacity to individualize therapeutic interventions by tracking the responses to treatments and forecasting treatment outcomes for specific patients (11). Biomarkers play a crucial role in the advancement of targeted cancer therapy, utilizing a range of targeted agents, including monoclonal antibodies (MoAb) (12).

Last but not least, in the evolving landscape of PM, the growing importance of biomarkers in pharmacogenomics is unmistakable. Notably, the FDA's compilation of a list of drugs linked to clinically validated pharmacogenomic biomarkers emphasizes their crucial role in customizing treatments (13)

3. Legal Frameworks in Europe

In the rapidly evolving landscape of PM, where tailored healthcare interventions depend on individualized patient data, robust legal frameworks are essential. This chapter explores the legal landscape governing PM in Europe, focusing on data protection and privacy regulations, intellectual property rights, research ethics, and informed consent.

3.1. Data Protection and Privacy Regulations

Since PM is based on individual characteristics, recognizing data sharing as a prerequisite for its successful implementation is vital, as it enables the collection, linkage, and reuse of diverse datasets encompassing molecular, clinical, phenotypic, and lifestyle information. The transformative potential of PM relies on the accessibility of data to multiple research groups, emphasizing the necessity for widespread sharing. This involves sharing both primary data, like human genome sequences, and secondary data previously utilized by original

collectors. Therefore, the necessity of a careful consideration of legal implications related to data sharing and privacy is crucial (14,15).

At the European Union (EU) level, in accordance with Article 168 of the "Treaty on the Functioning of the European Union" established in 2008, there is a dedication to guaranteeing a heightened level of safeguard for human health in all policies and undertakings within the EU. Additionally, the EU Charter recognizes the safeguarding of personal data, a subcategory of which are health data, as a fundamental right (14,16). The European Commission's recommendations in 2008 shifted their emphasis toward digital health and the cross-border interoperability of data. The objective was to outline guidelines for interoperable Electronic Health Records (EHR) and establish an integrated network for healthcare professionals and patients across EU, all in accordance with the fundamental rights of privacy and data protection (16).

The "General Data Protection Regulation" (GDPR) came into full legal force on May 25, 2018, applying to both the EU and the European Economic Area (EEA). This omnibus legislation establishes an all-encompassing legal structure designed to protect the personal data of Europeans and encourages conscientious handling of data for diverse valid objectives. GDPR brings about a substantial transformation in how organizations (hospitals, universities, research institutes, pharmaceutical industry) gather, utilize, and disseminate personal data (17). Its broad scope encompasses any data controller or processor, as well as any data subject located in the EU. Furthermore, the territorial scope (Article 3) of GDPR aligns with the data it safeguards, influencing the operations of organizations situated in various countries globally (14,17).

The primary goals of GDPR include protecting the data protection rights of individuals, particularly those participating in health research, and facilitating the "free movement" of personal data within the EU(17). GDPR outlines six key principles for handling personal information, emphasizing the importance of lawful, transparent, and fair processing. It requires explicit and legitimate purposes for data use, restricting reuse for other intentions. The regulation advocates minimizing data collection to what is necessary, ensuring accuracy and currency, limiting storage periods to original purposes, and enforcing secure data processing. The regulation empowers EU citizens with rights like access, consent withdrawal, data erasure, processing restriction, and prompt breach notifications (18).

The heightened transparency provisions of GDPR mandate that controllers inform data subjects, prior to processing and using clear language, about their intention to process the subject's personal data. Additionally, they are required to specify the lawful bases under Article 6 that justify the processing. In case of special category data (such as health or genetic data), controllers must identify the exception under Article 9(2) that allows for the processing of such data, since the processing of these special categories is generally prohibited (17). Specifically, Article 9 paragraph 2(j) states that data processing is allowed for scientific and research purposes, such as those required in PM. Additionally, "data concerning health" includes information derived from genetic testing, as clarified by Recital 35 of GDPR (17) .

Pseudonymized personal data, which are usually applied in clinical trials and scientific research, such as those key-coded, remain within the purview of personal data as outlined in GDPR. Pseudonymization involves a security measure that substitutes or eliminates information in a dataset that could identify an individual. On the contrary, the GDPR does not extend to anonymous data or data that has undergone anonymization. Anonymized data pertains to information that, when initially collected, was associated with an identifiable individual. However, through processes like scrambling or blurring that eliminate identifiers, the identity of the individual cannot be ascertained by reasonably foreseeable means. It is important to emphasize that the act of anonymization is recognized as a form of processing personal data (17). Anonymization techniques are usually used in research in case of data transfer, when the reconsent of the data subjects cannot be acquired.

In addition to individual country laws, there are universally applicable international laws like the "Universal Declaration of Human Rights" and the "European Convention on Human Rights", which emphasize the privacy rights of individuals, including the handling of personal information (18). Certain nations have also implemented extra security measures, beside those required by EU (19).

3.2. Intellectual Property Rights in Genomics Data

Intellectual Property Rights (IPR) can be understood as property rights, primarily involving intangible assets that safeguard innovations and creative works, serving as a reward for inventive and imaginative endeavors. IP law is guided by two fundamental principles: first, to ensure the public enjoys the advantages of IP, and secondly, to control and supervise competition in this domain (20).

Recent advances in biotechnology, particularly in molecular biology and genetics, have led to transformative changes in society, especially in medicine and healthcare. Gene sequences and their expression patterns, given their ability to enhance the identification and personalized understanding of various tumor types, have gained significant economic value when protected through IPR (19) . The convergence of biotechnology and IPR has opened up commercial opportunities, prompting industries to seek protection for biotechnological inventions. However, this intersection has presented unique challenges for IP laws. The conventional principles of IP laws have been expanded to encompass novel subjects like genes, proteins, and various single-celled and multi-celled living entities. These were previously excluded from the purview of IP regulations (20).

One of the most debated topics in discussions on biotechnology and IPR revolves around the eligibility of biotechnological inventions for patent protection. The conventional patent criteria, including patentable subject matter, novelty, non-obviousness (inventive step), utility (industrial applicability), and written description, face challenges when applied to biotechnology inventions, particularly those related to genetics. Human genes, in particular, have emerged as a highly contentious subject in patent law due to their diverse nature. Although there is a disparity in how member states of the EU handle patenting for biotechnology inventions, there are ongoing attempts to harmonize and unify patent laws. The European Patent Convention (EPC), which established in 1973, enables the submission and examination of a single patent application through the EPO. In 1998 the EU Directive 98/44/EC, commonly referred to as the Biopatent Directive, was adopted and serves as a supplementary tool for interpreting the EPC, providing additional guidelines and provisions, offering clarity to specific regulations regarding the patentability of biotechnological inventions, and addressing various aspects and potential ethical concerns associated with this field. Europe has outlined specific categories of subject matter that are either eligible or ineligible for patent protection in their respective legislations. Additionally, Europe incorporates a clause related to *ordre public* and morality to assess the patentability of biotechnological inventions (20).

On the global stage, the international patent framework faces challenges in addressing the new complexities introduced by biotechnology. This is primarily attributed to uncertainties and potential gaps within the text of the "Agreement on Trade-Related Aspects of Intellectual Property Rights" (TRIPS Agreement). The TRIPS Agreement establishes broad parameters for safeguarding biotechnological inventions, with Article 27.1 explicitly stating that patents should be granted for inventions in any technological field without discrimination, subject to specific conditions. This provision provides a legal basis for biotechnology patents, including gene patents, and imposes an obligation on member states to accommodate biotechnological innovations.

Beyond legal consequences, patents on genes and gene fragments carry substantial social and policy implications. These ramifications pertain to the accessibility of genetic research tools, advancements in genetic innovation, healthcare policies, the rights of patients, clinical practices, and the broader societal impact. The patenting of genetic testing, particularly in the diagnostic

realm, has become a contentious issue. Thus, diagnostic tests based on purely natural principles or phenomena cannot be patented (19,20).

The realm of IPR is continually broadening, with the regular emergence of new rights or the application of existing ones to relatively novel subjects, including genetic databases and human genes (20). A complicating element arises from the potential existence of additional IPR with data. In EU (excluding Switzerland), the protection afforded by copyright is supplemented by the sui generis regime specifically designed for databases (21). EU introduced the "European Database Rights Directive" to standardize protection across its member states. This directive safeguards a "collection of independent works, data, or other materials arranged in a systematic or methodical way and individually accessible by electronic or other means". Consequently, a database developer has the right to prevent the extraction and/or reuse of the entire or a substantial portion of the database's contents. However, it's important to note that the protection granted under this directive is restricted to individuals or legal entities residing in the EEA or in countries with similar protection mechanisms (20).

In order to address disparities in IPR, due to lack of harmonization between various jurisdictions, standardized contractual arrangements can be employed to delineate the rights of each involved party. In the field of biomedical research, Material Transfer Agreements (MTAs) are commonly utilized to regulate the sharing of human tissue and data among institutions, ensuring clarity regarding provenance (21).

3.3. Research Ethics and Informed Consent

Clinical research and trials necessitate a comprehensive, multi-faceted strategy. It goes beyond merely identifying and approving new drugs. Effectively managing a rare disease or cancer, for example, involves conducting intricate clinical investigations that combine drugs, companion diagnostics, advancements in surgical techniques, and novel radiotherapy approaches. Crucially, the integration of all available information, including biological samples and the growing significance of extensive data through big data technologies, is imperative(22).

EU has established a robust framework for clinical research, drawing upon ethical principles articulated in foundational documents such as the Helsinki Declaration, the "International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use - Good Clinical Practice" (ICH GCP), the Oviedo Convention, as well as principles enshrined in Human Rights and the Nuremberg Code. This framework encompasses key legislative instruments including the Clinical Trials Regulation 536/2014, the Directive 2004/23/EC regarding human tissues and cells, the Directive 2002/98/EC regarding human blood and blood components, the Regulation (EU) 2017/746 on in vitro diagnostic medical devices and the Regulation (EU) 2021/2282 on Health Technology Assessment (HTAR). Notably, the enforcement and governance of these regulations and directives are underpinned by GDPR, safeguarding personal data within the context of clinical research (22).

The Regulation 536/2014 addresses clinical trials on medicinal products for human use within the European Union. Key features of this regulation include a centralized EU portal and database for clinical trial information, a simplified application procedure, and a harmonized assessment process for multi-center clinical trials. The regulation emphasizes transparency, efficiency, and patient safety in the conduct of clinical trials.

The HTA Regulation, which is applicable from January 2025 onward, aims to enhance the accessibility of innovative health technologies, including medicines and specific medical devices, for EU patients. It promotes efficient resource utilization and elevates the quality of HTA throughout the Union. The framework establishes a transparent and inclusive structure, featuring a Coordination Group of HTA national or regional authorities, a stakeholder network, and rules governing the involvement of patients, clinical experts, and other relevant professionals in joint clinical assessments and scientific consultations (23,24).

GDPR delineates key provisions pertaining to scientific research. The establishment and roles of Data Protection Officers are detailed in Articles 37-39, while Articles 40 and 44-49 deal with codes of conduct and cross-border data transfers. Article 89 provides safeguards for processing personal data for scientific research purposes, offering a nuanced regulatory framework for the ethical and legal aspects of research within the GDPR (17).

In PM research, the management of information and data, particularly involving biospecimens and genetic details, raises critical legal and ethical issues related to consent and the privacy both of personal and familial health information (25).

The conditions governing consent have been strengthened to enhance data subjects' understanding of their consent regarding data processing, thereby reinforcing individuals' rights. The updated conditions for consent ensure that separate consent is required for distinct processing purposes in certain situations, and consent is deemed valid only if it can be withdrawn without any adverse consequences. It's crucial to note that consent represents just one of several legal bases for data processing under the GDPR. According to the GDPR (Art. 9(2)(a)), a request for consent must be presented distinctly, in an understandable and easily accessible manner, using clear and plain language. The specific purpose for processing, including sharing, should be clearly elucidated, and withdrawing consent should be as straightforward as granting it (17).

The primary objectives of informed consent within the Clinical Trials Regulation are threefold. Firstly, it aims to furnish comprehensive details about the study (e.g. duration, responsibilities and rights, associated risks, possibility of random assignment to control group) to ensure the participant is fully informed. Secondly, it addresses the future use of data, the disclosure of research results to participants, and the potential implications of unexpected and/or incidental genetic findings. Lastly, it emphasizes that patients, based on this information, make an informed decision on whether to participate in the study(19).

3.4. Healthcare Regulations and Reimbursement Policies

Healthcare regulations and reimbursement policies in the EU can vary among member states, as each country has its own healthcare system and policies. However, there are some overarching principles and frameworks that guide healthcare regulation and reimbursement in the EU.

- Regulatory Framework: EU has established a regulatory framework for medical devices, including in vitro diagnostic devices (IVDs). The “Medical Devices Regulation (MDR)” and “In Vitro Diagnostic Medical Devices Regulation (IVDR)” are key pieces of legislation that set standards for the approval and marketing of medical devices, including those related to precision medicine.
- Health Technology Assessment (HTA): HTA plays a significant role in the evaluation of the effectiveness, safety, and cost-effectiveness of healthcare technologies, including personalized medicine.EU has been working toward greater collaboration among member states in the field of HTA to ensure consistent evaluation and decision-making processes.
- Cross-Border Healthcare Directive: The “Cross-Border Healthcare Directive” allows EU citizens to access healthcare services in other member states and seek reimbursement from their home country. This directive may have implications for patients seeking PM treatments abroad.
- The “European Health Data Space (EHDS)” is an EU initiative designed to enhance the sharing of health data across member states. The primary goal of EHDS is to empower individuals by giving them control over their personal electronic health data and facilitating its secondary use. Additionally, EHDS aims to promote the development of a market for electronic health records (24).

PM has evolved from a research initiative to an established clinical concept. This transformation has elevated PM to a pivotal role, now acknowledged as an essential and integral component of the future of healthcare. This shift

in perspective has led to a strategic change, with PM transitioning from a primarily scientifically driven "bottom-up" development to a "top-down" approach. This new approach requires sustainable governance, comprehensive infrastructure, and stakeholder engagement, ensuring continuous research feedback and equal access to precision healthcare at regional or national levels (24).

Numerous European nations have made notable strides in integrating PM into their healthcare systems. The bottom-up approach is frequently grounded in regional networks, as observed in Sweden, Germany, and Italy. Conversely, the top-down method, involving government funding for national genome initiatives, has been implemented in countries such as England, France, Denmark, and Spain. There is a possibility that, at a certain stage, these two approaches may merge with established healthcare structures, providing an opportunity for national initiatives to complement existing systems (24).

Reimbursement policies for healthcare services and treatments, including PM, are determined at the national level, since each member state has its own healthcare system, financing mechanisms, and reimbursement policies (24). There are two reimbursement models that are used in PM, the traditional and the risk sharing ones. Conventional, non-risk-sharing reimbursement models are employed for the compensation of gene, cell, and targeted therapies, as well as biomarkers, genetic, and genomic tests in the healthcare sector. In Europe, confidential rebates are applied to payment models like Diagnosis-Related Groups (DRGs) (26).

Reimbursement for molecular diagnostic tests has been facilitated by integrating them into established payment models like DRGs and negotiated tariff-based payments at both local and national levels. This approach is observed in EU5 countries. Alternatively, the costs of diagnostics may be covered through allocations from state and hospital budgets or by pharmaceutical companies (26).

Lastly, healthcare reimbursement policies usually establish a "benefit basket," encompassing medical procedures, goods, and services that are eligible for (partial) reimbursement within the healthcare system. This benefit basket typically comprises one or more benefit catalogs, which are comprehensive listings of medical procedures, goods, or services. The catalog could adopt a positive listing, incorporating these procedures, activities, or goods into the benefit package, or a negative listing, excluding them. Descriptions of medical procedures in the catalog could either be generic (e.g., based on indication, test technique, or the biomarker under investigation) or involve a specific product reference within the procedure (27).

4. Ethical Considerations in Precision Medicine

Currently, the field of bioethics is advancing swiftly, blending the principles of science, medicine, law, and philosophy within the healthcare domain. Instances where ethical considerations do not necessarily align with legal permissibility prompt a discourse on revising laws to harmonize with the ethical dimensions of the issue (19).

4.1. Informed Consent and Patient Autonomy

Autonomy is a foundational principle in bioethics, crucial for informed consent in medical treatments or diagnostic procedures. Individuals are obligated to comprehend all pertinent information (associated risks and benefits) to make independent choices without coercion. Nevertheless, individuals must contemplate the extent to which their individual decisions should be honored in light of other individual considerations. This aligns with the harm principle, which supports respecting autonomy unless decisions significantly threaten others (19).

Over the course of several decades, safeguarding the autonomy of individuals involved in research and those contributing data has been contingent upon the principle of informed consent. Initially conceived as a mechanism for autonomous approval in research endeavors or medical procedures, informed consent has evolved to encompass various additional roles, such as delineating individual

preferences regarding data reuse and the disclosure of incidental findings (15).

Three forms of consent exist: explicit, implicit, and opt-out consent. Explicit consent involves presenting the purpose, use, handling, and disclosure of personal information, providing the option to agree or disagree—particularly vital for clinical trials and medical record retention, also known as opt-in consent. Implicit consent is assumed for both the data subject and collector, often evident during data collection (e.g., a doctor taking blood samples for lab tests). In opt-out consent, participants are informed about the purpose of consent with the choice to decline; if not declined, consent is considered provided (18).

The primary challenge associated with consent emerges during data sharing and linkage, a necessity in the data pre-processing phase of health data analytics, involving diverse sources like hospitals and insurance companies. Two consent approaches exist: static consent and dynamic consent. In static consent, approval is sought for all future data usage during collection, typically using paper-based methods. However, it lacks adaptability to changing environments and evolving requirements, such as repurposing data for different health projects not originally consented for. In contrast, dynamic consent offers advantages. It is an informed and personalized consent involving two-way communication between the data subject and custodian, allowing updates and various consent types. Additionally, the subject retains control over health data usage, with the ability to revoke consent through the interface. Notably, consent travels with the shared data, and participants gain access to research results (18).

In the context of obtaining consent from minors or individuals unable to provide consent, specific safeguards are in place. The involvement of parents or duly authorized individuals in decision-making on behalf of minors necessitates a careful consideration of the minor's best interests, with due attention to preserving their individuality. It is crucial to underscore that the objections raised by the minor/ person unable to consent must be honored, irrespective of the consent provided by their parents or authorized representatives (19).

Ethical concerns about patient autonomy arise with incentives for research participation, such as payments or gifts. Evidence shows economic incentives boost participation, but socioeconomic factors can introduce bias. Participants should possess a clear understanding of the conditions governing partial or non-payment. Typically, incentives should be set at a level that avoids exerting coercive or undue influence on the decision-making process regarding study participation. These incentives may include coverage for transportation, meals, and compensation for lost work hours during visits (19).

4.2. Data Privacy and Security

Balancing personal privacy with rights to healthcare, a healthful environment, and the judicious utilization of public funds poses ethical challenges in data privacy and security. EU health research follows a strong ethical framework with verified data handling protocols. Ethics committees evaluate risks and benefits, ensuring data use is proportionate to societal benefits. (28).

The main methods for ensuring data privacy encompass anonymization and pseudonymization. Anonymization includes randomization, which breaks direct data-individual links by altering data integrity, and generalization, which dilutes data attributes by using broader categories, such as "region" instead of "street" and ranges of years instead of specific years. Despite employing diverse methods in anonymization, it has been demonstrated that these techniques are not adequate to ensure privacy (18).

Pseudonymization involves substituting one attribute in a dataset with another to diminish the linkability between the original identity of a data subject and the dataset. Various techniques are employed for pseudonymization, including encryption with a secret key, the use of hash functions, keyed-hash functions with stored keys, deterministic encryption, and tokenization and masking (18).

Finally, the ethical imperative of minimizing the risk of information leakage or potential breaches is also of critical importance within the domain of data privacy and security.

4.3. Ethical Issues in Genetic Testing and Risk Assessment

Within the realm of in vitro diagnostic tests, genetic testing emerges as a crucial player influencing therapeutic decisions and personalized interventions. The two primary categories of genetic testing are Laboratory Developed Tests (LDTs) and genetic test kits. LDTs, prevalent in practice, originate within specific laboratories where patient samples undergo analysis, constituting a form of in-house genetic testing. Conversely, genetic test kits encompass a bundle of reagents and analytical information marketed to multiple testing laboratories. Noteworthy are the instances of certain genetic tests directly reaching consumers through Direct-to-Consumer (DTC) channels, a phenomenon that sparks considerable ethical discourse (25).

Challenges in genetic decision-making stem from the intricate nature of genetic mechanisms and their interactions with environmental factors, creating uncertainty about genetic disease causes and limited patient information. This complexity affects informed consent and necessitates careful consideration, as individuals may face significant decisions regarding family planning, including pregnancy continuation or termination, and prenatal diagnosis (29).

Safeguarding privacy in genetic testing requires careful attention due to the implications for both individuals and their family members. Disclosure decisions should consider the condition's severity, availability of effective treatments or preventive measures, and diagnostic reliability. Balancing patient confidentiality with third parties' autonomy over relevant genetic information is crucial, emphasizing the ethical complexity of sharing genetic data against individuals' wishes (29).

Prenatal diagnosis detects hereditary, infectious, iatrogenic, or environmental conditions, significantly influencing reproductive choices by providing fetal insights before birth. It is conducted not on the individual seeking the examination but on the conceived fetus, and impacts personal and familial aspects. Result communication should be within a non-directive counseling framework, respecting the autonomy of the pregnant woman and couple (29).

Finally, genetic information obtained through genetic testing, including increased susceptibility to future diseases, disorders, or conditions, should not be exploited for genetic discrimination. For example, the possibility of utilizing such information to deny employment based on an individual's predisposition to current or prospective medical issues has prompted numerous countries to implement legal measures (19).

In the contemporary landscape, the prevalence of easily accessible direct-to-consumer genetic testing (DTC GT) on the internet is on the rise. These tests, being products of PM, gather both potential risks and benefits (19).

Several challenges arise, encompassing a broad range of ethical issues. These involve concerns such as insufficient or problematic engagement of healthcare professionals, the effectiveness of pre- and post-test counseling, the scientific validity and utility of the testing, the insufficient interpretation of the results, deceptive advertising practices, the potential strain on healthcare systems, illicit testing in minors or third parties, the secondary use and privacy of consumer data, nonconsensual utilization and commercialization of testing, and regulatory issues related to DTC GT. Moreover, recent literature suggests that ethical concerns related to DTC GT remain unresolved. These issues have the potential to become more pronounced as the technology continues to evolve, and the range of services offered expands (30).

5. Regulatory Gaps and Challenges

PM offers significant advancements in diagnosis, treatment, and disease prevention. However, it faces regulatory challenges including data protection, privacy issues, and the need for standardized consent mechanisms. Ethical considerations such as equitable access and potential biases are also significant. Non-scientific barriers like regulatory hurdles, high development costs, and the need for extensive stakeholder collaboration further hinder progress.

Regulatory Uncertainty

Currently, regulatory uncertainty remains a notable challenge in PM R&D and implementation. The central problem is that certain current regulations seem unsuitable for PM, experiencing a lack of harmonization that currently hinders the progress of PM development (25). Moreover, the absence of harmonized procedures for the constituent elements of PM contributes significantly to uncertainty in regulatory approval (31).

Informed Consent

For many years, safeguarding the autonomy of research participants and data contributors has hinged on the concept of informed consent. Over time, informed consent has taken on additional roles, such as articulating individual preferences regarding data reuse and the disclosure of incidental findings. This expansion has resulted in a functional overload. While informed consent remains a vital prerequisite for utilizing secondary data, the current practices do not provide the necessary level of detail for data contributors to exercise meaningful control-especially concerning the diverse data types essential for PM (15).

The extent of informed consent in the context of PM, in particular, is intricate and significant. Typically, agreeing to participate in research involving an individual or their tissues pertains to a specific research activity that can be clearly outlined, allowing for meaningful consent or refusal based on an understanding of associated risks and alternatives. A challenge within the PM research domain arises from the question of whether a patient can provide a generalized consent for future research without knowledge of the specific nature and risks of that research. Often in PM there is a requirement to reassess tissue samples for research outcomes different from the initially specified purpose. Obtaining re-consent from tissue donors for an altered research objective may be impractical or impossible, and the necessity for such re-consent in all situations remains unclear (25).

Clinical Trials

While clinical trials play a crucial role in ensuring patient safety, many observers have suggested that they pose a significant obstacle to the prompt and efficient translation of research into therapy, particularly in PM. There exists a profound tension between the goals of PM, which aim to provide tailored therapies for smaller, stratified patient populations, and the standard clinical trial designs that evaluate efficacy in large and generalized patient cohorts. Initially, smaller clinical trial formats yield less compelling evidence regarding safety and effectiveness because of the limited patient pool involved. These compact trials lack the statistical robustness required to identify efficacy, particularly when the anticipated effect size is minimal. Additionally, in the absence of a comprehensive study involving a large, representative population, it becomes challenging to comprehensively assess the drug's benefit-to-risk ratio (25).

Data protection

Related to the data protection, the issue of data ownership arises in connection with collections of health information. These collections involve various stakeholders, each possessing distinct rights to their data (21).

As previously noted, conventional de-identification and pseudonymization techniques fall short in adequately mitigating the risk of re-identification. This risk is especially heightened when handling clinical and omics data (21). Ensuring data security and privacy for data-in-use presents a challenging task since it involves data computation (18).

Companion Diagnostics

An additional challenge encountered within the domain of PM pertains to Companion Diagnostics, which are predominantly used for in vitro assays or genetic tests, and are typically subject to regulatory oversight as medical devices (25). In the field of PGx, the primary focus lies on predicting the outcomes of drug interventions. The challenge with CDx is that the current reimbursement policies often do not support the synchronization of decision-making for both components. This discrepancy is attributed to historically divergent pathways for reimbursement decisions between in vitro diagnostics and medications. Consequently, this misalignment frequently results in the

reimbursement of the medication without corresponding reimbursement for the CDx. The lack of simultaneous reimbursement decisions can lead to suboptimal clinical decisions, potentially hindering the value of precision medicine practices (27).

Policy makers

For policymakers, the driving factors endorsing PM encompass the establishment of health policies that are secure, efficacious, and transparent, as well as demonstrating fiscal responsibility in health expenditure and safeguarding patient rights. Challenges and gaps are commonly arisen from a restricted comprehension of patient viewpoints regarding test utilization, insufficient awareness of the effects of testing on health efficiencies and outcomes, and conflicting priorities in health policy issues that may not prioritize the impact of testing, as well as inadequate supervision of diverse insurance and reimbursement schemes (31,32). Moreover, there is a lack of understanding of the clinical research needs, with legislation primarily concentrating on healthcare or product commercialization rather than clinical research. Despite the regulations pertaining to clinical trials, IVDs, medical devices, and data protection, this siloed approach may render the overall framework inconsistent and potentially detrimental to the EU's ability to advance swiftly in the realm of PM (22).

6. Recommendations for Improving Precision Medicine Regulations

The emerging challenges stemming from informed consent and data protection necessitate innovative technological solutions. Emerging digital consent technologies alleviate the burden on data donors by eliminating the need for intricate upfront decisions, enabling a more flexible, case-by-case consideration throughout the diverse applications of the data. For instance, innovative cryptographic techniques and decentralized ledger technologies like blockchain have recently emerged as potential avenues for enhancing the security of health data (15).

In addition, ensuring the security of physical devices and critical infrastructures (healthcare facilities, cloud servers etc.) is imperative. The implementation of a robust secure data backup system becomes essential to facilitate data recovery in the event of risks or system failures. Additionally, conventional access control mechanisms play a pivotal role in data security by regulating user access to sensitive information. Multi-factor authentication, like passwords, biometric scans, cryptographic tokens, and RFID cards, stands as a standard approach within access control. Intrusion Detection Systems (IDS) and Intrusion Prevention Systems (IPS) can serve as crucial components in bolstering security (18).

To address the challenge of data ownership, any viable solution must take into account not only data protection laws and research ethics regulations but also IP laws, including copyright, as well as agreements related to data use or material transfer (MTAs) (21).

Last but not least, propelling PM to the forefront demands a holistic approach that addresses several critical facets. Interoperability of frameworks stands as a linchpin, fostering seamless integration and collaboration across diverse systems. Equally crucial is the imperative for policymakers to be well-informed about the ever-evolving landscape of PM, underscoring the need for continuous education and awareness. Establishing multidisciplinary committees in policy-making endeavors ensures a comprehensive understanding of the multifaceted challenges and opportunities. Furthermore, engaging all stakeholders, from healthcare professionals to patients, industry leaders, and researchers, is paramount to cultivate a collective vision for the advancement of PM. Finally, an unwavering commitment to vigilance for advancements is essential to keep pace with the dynamic nature of the field, positioning EU as a trailblazer in the relentless pursuit of groundbreaking achievements in PM.

7. Conclusions

The exploration of PM has illuminated the profound impact of it across various medical fields and its evolving relationship with the legal frameworks within EU. The identified key findings also underscore its future perspectives,

particularly the promising advancements in cell and gene therapies.

The identified regulations within the EU represent significant strides toward creating a legal infrastructure for PM. However, gaps exist in the legal framework and the various healthcare policies and reimbursement models within EU, as well as worldwide.

Acknowledging the evolving nature of PM, there is a pressing need for proactive measures to address current and potential gaps. The establishment of multidisciplinary committees or a competent body in EU dedicated to PM can play a crucial role in promptly adapting to new advancements, ensuring patient safety, and facilitating the seamless integration of PM applications into healthcare systems. Finally, the symbiotic relationship between PM and European law is evident, recognizing both the potential and the challenges that come with the integration of cutting-edge medical technologies into legal frameworks. The ongoing efforts to bridge the gaps and proactively address emerging issues reflect a commitment to creating an environment where PM can thrive, benefitting individuals and society as a whole.

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Ηλεκτρονικό Περιοδικό της Εθνικής Επιτροπής Βιοηθικής & Τεχνοηθικής

Ανασκοπήσεις - Reviews

Interreligious perspectives on Surrogate Motherhood

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Abstract

Surrogate motherhood raises a variety of ethical, legal, theological, and sociological questions. Discussions on this topic often become heated, particularly when considering the use of a woman's body to carry a pregnancy on behalf of another individual—married or unmarried, male or female—with an ovum that, in most cases, has no biological connection to her and is legally recognized as belonging to the commissioning party or parties post-birth. On one side, issues of self-determination, solidarity, and compassion are debated, while on the other, dignity, the sanctity of life, commodification, and exploitation are concerns. This article, without overlooking these significant issues, attempts an interreligious examination of surrogate motherhood to elucidate how the three major monotheistic religions, along with Hinduism and Buddhism, assess, interpret, and understand this practice. The aim is to highlight both converging and diverging positions across different views and to more fully comprehend the various theological and cultural dimensions that shape the contemporary bioethical understanding of this issue.

Keywords: Surrogate motherhood, assisted reproduction, interreligious bioethics.

Διαθρησκειακή θεώρηση της παρένθετης μητρότητας

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Περίληψη

Ποικίλα ηθικά, νομικά, θεολογικά και κοινωνιολογικά ζητήματα εγείρονται γύρω από την πρακτική της παρένθετης μητρότητας. Οι σχετικές συζητήσεις πολλές φορές γίνονται έντονες καθώς εξετάζεται η δυνατότητα της χρήσης του σώματος της γυναίκας και η δυνατότητα κυοφορίας για λογαριασμό ενός άλλου ατόμου (εγγάμου ή αγάμου, ανδρός ή γυναικός) ενός γονιμοποιημένου ωαρίου που στις περισσότερες περιπτώσεις δεν συνδέεται βιολογικά μαζί της και μετά την γέννηση αναγνωρίζεται νομικά στον εντολέα ή στους εντολείς. Από την μία πλευρά τίθεται το ζήτημα της αυτοδιάθεσης, της αλληλεγγύης και της συμπόνιας και από την άλλη πλευρά το ζήτημα της αξιοπρέπειας, της ιερότητας της ζωής, της εμπορευματοποίησης και της εκμετάλλευσης. Το παρόν άρθρο χωρίς να αγνοεί τα τόσο ενδιαφέροντα ζητήματα επιχειρεί μία διαθρησκειακή εξέταση της παρένθετης μητρότητας, με σκοπό να διαφανεί πως οι τρεις μεγάλες μονοθεϊστικές θρησκείες, αλλά και ο Ινδουισμός και ο Βουδισμός αξιολογούν, ερμηνεύουν και κατανοούν την εν λόγω πρακτική. Σκοπός του άρθρου είναι να καταστούν εμφανείς τόσο οι συγκλίνουσες, όσο και οι αποκλίνουσες θέσεις των διαφορετικών θεωρήσεων και να κατανοηθούν πληρέστερα οι διάφορες θεολογικές και πολιτισμικές διαστάσεις που διαμορφώνουν τη σύγχρονη βιοηθική αντίληψη για το εν λόγω ζήτημα.

Λέξεις κλειδιά: Παρένθετη μητρότητα, υποβοηθούμενη αναπαραγωγή, διαθρησκειακή βιοηθική.

1. Introduction

In the Greek language, the term "surrogate mother" refers to a woman who carries the fertilized ovum of another woman or, more broadly, a woman who carries an embryo which, upon birth, will not be raised by her.[1] This term is derived from the Greek "παρεντίθημι" (παρ(α)- + ἐν + τίθημι), signifying accurately the woman who is interposed or "inserted" between the biological mother and the child.[2] Similarly, in English, the term "surrogate mother" originates from the Latin "surrogatus," meaning substitute, and denotes a woman chosen to act in someone else's place.[3] Thus, a surrogate mother is the woman assigned to carry a pregnancy on behalf of another person or persons, who will become the parent or parents of the child immediately after birth and assume all parental rights and responsibilities. The terms "φέρουσα (carrier)" and "υποκατάστατη (substitute)" are often used interchangeably to describe this practice. However, it should be clarified that the former term refers to cases where the biological mother's ovum is used, while the latter refers to cases where both the uterus and the ovum are provided by the surrogate.[4]

Although the practice of surrogate motherhood has its roots in antiquity, it has emerged in a different form in recent years, raising various ethical, theological, legal, and sociological issues. Initially, surrogate motherhood referred to a woman who, for compensation, provided both her ovum and uterus through the technique of intrauterine insemination. With the development of in vitro fertilization, it became possible to create an embryo in vitro, which was then implanted into the surrogate mother's uterus, without any genetic relation to her. Consequently, there are two categories of surrogate mothers. In the first scenario, insemination occurs using the sperm of the husband of the woman unable to carry a pregnancy or a third party's sperm.[5] In the second scenario, in vitro fertilization is included.[6] That is, the embryo, from the gametes of the prospective parents or from the fertilization of the egg or sperm of the couple or third parties, is produced in vitro and implanted in the surrogate. In both cases, there are two forms of artificial fertilization, homologous and heterologous. Homologous fertilization refers to cases where both the egg and the sperm belong to the spouses, and heterologous refers to cases where the sperm, the egg, or both are

[1] Charalambakis Ch. Χρηστικό Λεξικό της Νεοελληνικής Γλώσσας (Practical Dictionary of Modern Greek Language.). National Printing Office, Athens 2014: 1021.

[2] Babiniotis G. Λεξικό της Νέας Ελληνικής Γλώσσας (Dictionary of the Modern Greek Language). Lexicology Center, Athens 1998: 1355.

[3] Stavropoulos G., Hornby A. Oxford English-Greek Learner's Dictionary. Oxford University Press, Oxford - New York, 2001: 741.

[4] Βασικές Θέσεις επί της Ηθικής της Υποβοηθούμενης Αναπαραγωγής (Basic Positions on the Ethics of Assisted Reproduction). https://www.bioethics.org.gr/03_b.html#2.

[5] Sareidakis E. Βιοηθική - Ηθικά προβλήματα των νέων βιοϊατρικών τεχνολογιών (Bioethics - Ethical issues of new biomedical technologies). Papazisis Publications, Athens 2008: 126.

[6] Idem, p. 127.

from different individuals.[7] Thus, a fundamental problem arises from the involved parties, as a child in some cases may be connected to up to five individuals. Namely, the parents who raise the child and to whom the child is legally recognized, the surrogate mother in whom the fertilized eggs were implanted, and the donors of the sperm and egg if these are taken from different individuals. Therefore, with this practice, a child can have up to three mothers (the genetic, the gestational, and the social) and up to two fathers (the genetic and the social).[8]

Most countries, at least until the recent past, did not have specific legislation for surrogate motherhood, causing considerable concern. In recent years, more and more countries are implementing necessary legal regulations, given that surrogate motherhood is becoming a global commercial phenomenon. This is highlighted by the notable number of women willing to "offer" their wombs for compensation,[9] and the total cost exceeding $1 billion annually (estimated to range from $2.3 billion to $6 billion annually)[10]. This growth in surrogate services is driven either by couples unable to conceive on their own or by single individuals asserting their right to parenthood.[11] Additionally, there are cases of posthumous fertilization, where a man wishes to implant his deceased wife's frozen eggs into a surrogate or a woman, beyond reasonable childbearing age, wishes to have the fertilized eggs of her deceased husband implanted in a surrogate.

Therefore, there is a need to establish robust legal frameworks to regulate the issue, aiming to safeguard the rights of all involved parties. It is crucial to pay special attention to the rights of the children to be born and to assess the risks to which both the surrogate and the children are exposed (medical risks, changes in the commissioners' stance, citizenship).[12] While the discussion of the ethical dilemmas arising from the practice of surrogate motherhood is particularly interesting, this article attempts an interreligious perspective on the issue, aiming to clarify the stance of various religions towards the practice of surrogate motherhood.

[7] Nikolaidis A. Από τη Γένεση στη Γενετική (From Genesis to Genetics). Grigoris Publications, Athens 2006: 156.

[8] Mantzaridis G. Θεολογική θεώρηση της υποβοηθούμενης αναπαραγωγής (Theological consideration of assisted reproduction). ΕΕΘΣΘ 2000, 10: 97-99.

[9] See also: Vantsos M. Surrogate motherhood: An act of altruistic offering or commodification of the body? KOSMOS - Scientific Journal of the Department of Pastoral and Social Theology, Aristotle University of Thessaloniki, Thessaloniki 2020: 85-97.

[10] Deonandan R. Thoughts on the ethics of gestational surrogacy: Perspectives from religions, western liberalism, and comparisons with adoption. J Assist Reprod Genet 2020, 37: 269-279. https://doi.org/10.1007/s10815-019-01647-y

[11] Nnamuchi O. Surrogacy, Religious Culture, and the Imperatives of the Law: Any Caveats for Law Makers?. In: Duruigbo, E., Chibueze, R., Gozie Ogbodo, S. (eds) International Law and Development in the Global South. Palgrave Macmillan, Cham 2023. https://doi.org/10.1007/978-3-031-13741-9_15.

[12] See also: Protopapadakis E. Ο νέος εφιάλτης του Σολωμόντος, παρένθετη μητρότητα και Βιοηθική (Solomon's new nightmare, surrogacy, and Bioethics).. In: Μάνος Α. (ed.) Άνθρωπος και Τεχνολογία: Η Παγκόσμια Πολιτική και Οικονομική Κρίση. Dardanos Publications, Athens 2011: 85-94.

2. The stance of Orthodox Church

The Orthodox Church, comprising 15 autocephalous local Churches, has not adopted an official and unified stance on the issue of surrogate motherhood. However, in 2002, the Special Synodal Committee on Bioethics of the Church of Greece made comments and suggestions concerning the bill on Medical Assistance in Human Reproduction. The committee examined the issue of surrogate motherhood, particularly with reference to Article 1458.

Initially, the committee positively evaluated the state's interest in facilitating women who are unable to conceive, as well as the requirement for judicial permission. It then pointed out several issues that "justify reservations" regarding the practice of surrogate motherhood, including:

Various legal, social, and psychological problems that could arise for those involved. The lack of measures regarding the potential use of this method by foreign women in Greece, noting that it had not yet been permitted in other European Union countries. This could facilitate reproductive tourism, as individuals from countries where surrogate motherhood is banned could turn to Greece to have a child carried by a woman living in the country. The absence of any reference to the commercialization of the entire process and no measures to protect against such a possibility. The Committee also made three significant observations about the issue under review: The developing bond with the embryo during pregnancy is an essential and integral part of both motherhood and embryonic development. Thus, continuing the relationship between the surrogate mother and the child wrongs the genetic parents, while severing this relationship wrongs the surrogate mother. In any case, both solutions primarily wrong the child and disrupt family cohesion. The intervention of the gestational carrier in the sacred relationship between the genetic parents and the child is not without consequences. The committee posed several important questions, such as what happens if the genetic parents die or wish to terminate the pregnancy after prenatal testing or due to other reasons (e.g., divorce), while the surrogate mother refuses? Is surrogate motherhood a paid offer or an act of mutual benefit? If it is the former, what terms define the compensation or obligations of the gestational carrier towards the parents and vice versa? After examining these points, the Committee suggested withdrawing the article and delaying this regulation until a more appropriate time, mainly to identify the exceptional conditions under which only the court's permission would be granted.[13]

In 2006, the Church of Greece issued a document that was approved by the Holy Synod titled "Basic Positions on the Ethics of Assisted Reproduction." This text highlights that while the possibility of gestation by a surrogate or substitute mother may have a positive aspect in that it serves pregnancy in love, the developing bond with the embryo during pregnancy is an essential and integral part of not only motherhood but also embryonic development. The continuation of the relationship between the surrogate mother and the child wrongs the genetic parents, while its termination also wrongs the surrogate mother and, above all, wrongs the child. For this reason, especially because such a practice disrupts family cohesion, the

[13] Σχόλια και Προτάσεις επί του Νομοσχεδίου για την Ιατρική Υποβοήθηση στην Ανθρώπινη Αναπαραγωγή (Comments and Suggestions on the Bill for Medical Assistance in Human Reproduction). https://www.bioethics.org.gr/03_b.html#2.

Church finds it difficult to bless such a deviation from the natural path.[14]

On the other hand, the Russian Orthodox Church has positioned itself on bioethical issues through an extensive encyclical issued in 2000. Although the encyclical recognizes and positively evaluates the parents' desire to have children, it simultaneously emphasizes that the end does not justify the means, thus rejecting most modern methods of assisted reproduction. Specifically, the practice of surrogate motherhood, whether there is a financial agreement or not, is characterized as unnatural and morally unacceptable. According to the Russian Orthodox Church, "this method presupposes the destruction of the deep emotional and spiritual intimacy that is formed between the mother and the baby during pregnancy." The encyclical continues, stating that "surrogate motherhood" harms both the carrier, whose maternal feelings are violated, and the child, who may subsequently suffer from a crisis of self-awareness.[15] Furthermore, in 2013, the Russian Orthodox Church decided that infants born from a surrogate mother would not be baptized unless there is sincere and active repentance by the parents for choosing this specific practice. This stance underscores the church's strong ethical opposition to surrogate motherhood and its significant concerns about the emotional and spiritual impacts on both the child and the surrogate mother. [16]

The Church of Greece, although it "struggles to bless" the use of surrogate motherhood, does not completely reject it, unlike the Russian Orthodox Church. In any case, the issue must be examined by the Pan-Orthodox Bioethics Committee, whose proposal needs to be ratified by a new, anticipated Holy and Great Council, in order to achieve a common and unified decision among all Orthodox Churches.

It is noteworthy that in the Holy Scripture, specifically in the Book of Genesis, we find the biblical narratives of Abraham and Sarah, and Rachel and Jacob, which could prove particularly useful for the topic under examination as they provide significant testimony to "surrogate motherhood" in the pre-Christian era. Abraham, a Patriarch of Israel and an ancestor of Jesus Christ, settled in the land of Canaan in his old age with his wife Sarah. There, Abraham lamented to God about being childless, fearing that his relative Eliezer from Damascus would inherit his estate (Gen. 15:2-3). However, God responded to his complaint, assuring

[14] Βασικές Θέσεις επί της Ηθικής της Υποβοηθούμενης Αναπαραγωγής (Basic Positions on the Ethics of Assisted Reproduction). https://www.bioethics.org.gr/03_b.html#2.

[15] See also: 13. Ladas I. Η απόφαση της Εκκλησίας της Ρωσίας περί απαγορεύσεως της τελέσεως του μυστηρίου της βαπτίσεως σε βρέφη που έχουν γεννηθεί μέσω παρένθετης μητέρας και η ανάγκη κοινής αντιμετωπίσεως των Βιοηθικών Ζητημάτων από την Ορθόδοξη Εκκλησία (The decision of the Church of Russia on the prohibition of the sacrament of baptism for infants born through surrogate motherhood and the need for a common approach to bioethical issues by the Orthodox Church). KOSMOS - Scientific Journal of the Department of Pastoral and Social Theology, Aristotle University of Thessaloniki, Thessaloniki 2020: 129-137.

[16] Κείμενο / Απόφαση της Ιεράς Συνόδου της Εκκλησίας της Ρωσίας με ημερομηνία 26 Δεκεμβρίου 2013 (Text / Decision of the Holy Synod of the Church of Russia dated December 26, 2013). О крещении младенцев, родившихся при помощи «суррогатной матери». http://www.patriarchia.ru/db/text/3481024.html.

him that he would not remain childless and that his own offspring would inherit him (Gen. 15:4-5). Sarah, although 90 years old, became pregnant, according to Divine Revelation, and bore Isaac. However, ten years before Isaac's birth, to ensure Abraham would not remain childless, Sarah encouraged him to conceive a child with Hagar, her Egyptian maid; legally, the child would also belong to her. [17] Specifically, Genesis 16:2 states, "And Sarai said unto Abram, Behold now, the Lord hath restrained me from bearing: I pray thee, go in unto my maid; it may be that I may obtain children by her (εἶπε δὲ Σάρα πρὸς Ἄβραμ· ἰδοὺ συνέκλεισέ με Κύριος τοῦ μὴ τίκτειν· εἴσελθε οὖν πρὸς τὴν παιδίσκην μου, ἵνα τεκνοποιήσωμαι ἐξ αὐτῆς)."[18] Through this arrangement, Ishmael was born from Hagar. Similarly, in another biblical narrative, it is mentioned that Rachel, unable to conceive naturally, said to Jacob, "Here is my maid Bilhah, go in unto her; and she shall bear upon my knees, that I also may have children by her (ἰδοὺ ἡ παιδίσκη μου Βαλλά· εἴσελθε πρὸς αὐτήν, καὶ τέξεται ἐπὶ τῶν γονάτων μου, καὶ τεκνοποιήσομαι κἀγὼ ἐξ αὐτῆς)" (Gen. 30:3).[19] Indeed, when Bilhah bore Jacob's son, Rachel said, "God hath judged me, and hath also heard my voice, and hath given me a son (ἔκρινέ μοι ὁ Θεὸς καὶ ἐπήκουσε τῆς φωνῆς μου καὶ ἔδωκέ μοι υἱόν)" (Gen. 30:6). [20]

The concept of surrogate motherhood in the aforementioned biblical narratives is not understood in modern terms, nor does it involve in vitro fertilization. Nevertheless, it is of significant importance that Sarah requested the child conceived naturally by herself and Abraham to be legally recognized as her own. Thus, with today's understanding, we can speak of a commissioning party to whom the child is legally recognized as offspring, without whom the entire process would not have occurred and essentially no birth would have taken place. Additionally, it is particularly noteworthy that before asking Hagar to carry the child in place of Sarah, the couple had prayed to God for offspring. It can therefore be argued that the desire of a couple to have descendants and then the effort to find the means to do so is rooted in the Old Testament. In any case, the conclusions one can draw from these biblical narratives are very important for the study of this subject not only for the Orthodox Church and other Christian churches and denominations that accept the Holy Scripture, but also for the three monotheistic religions, also known as the Abrahamic faiths.

[17] Christinaki El. Ιστορική Πορεία της Γυναίκας στη Βίβλο και Ισότητα των Δύο Φύλων (The Historical Journey of Women in the Bible and the Equality of the Two Genders), Symmetry Publications, Athens 2005: 153.

[18] «Είπε η Σαρα προς τον Αβραμ· "ιδού, ο Κυριος με έχει εμποδίσει να συλλάβω και γεννήσω τέκνον. Λοιπόν, πήγαινε εις την δούλην μου, δια να αποκτήσω, έστω και από αυτήν, ένα τέκνον"».

[19] «Ιδού, η δούλη μου η Βαλλά, πάρε την και θα γεννήση παιδί εις τα γόνατά μου και θα είναι σαν να έχω γενήσει εγώ. Το τέκνον της θα είναι ιδικόν μου».

[20] «ο Θεός μου έδωσε το δίκαιόν μου, ήκουσε την προσευχήν μου και μου εχάρισε παιδί».

3. The stance of other Christian Churches and Christian denominations

The Roman Catholic Church does not accept the practice of surrogate motherhood and considers it incompatible with Roman Catholic doctrine. According to its teachings, techniques that involve the separation of the conjugal act, by incorporating a third party outside of the marriage, are deemed unethical.[21] The central concern of the Roman Catholic Church is how these technologies impact human life. The stance of the Roman Catholic Church is that a medical intervention is ethical if it assists the marital act in achieving pregnancy but is unethical when the intervention "replaces" the marital act.[22]

Pope Francis has explicitly opposed surrogate motherhood, calling for its global prohibition. He has argued that the practice, often driven by profit motives, inflicts harm both on the mothers and the children involved. In this context, he has spoken about the commodification of pregnancy, describing it as a serious violation of dignity for both the woman and the child, and has advocated for a worldwide ban on the practice. This stance reflects the Church's broader ethical concerns regarding human dignity and the natural processes of human reproduction.[23]

Conservative Catholic thought condemns surrogate motherhood as an intrusion into the sanctity of marriage. However, when a child is born through a surrogate mother, its adoption by the couple could be considered an ethical act, provided that the surrogate is deemed to have "abandoned" the child and thus her maternal responsibilities. Whether the parents or the surrogate mother have a genetic relationship with the child does not matter in cases of abandonment. Therefore, the child, regardless of the method of its birth, can become a member of the Roman Catholic Church.[24] This approach underscores the Church's focus on the welfare and rights of the child, transcending the circumstances of birth in favor of providing a nurturing and legitimate familial and religious environment.

The Anglican Church, like other Protestant Churches and denominations, appears to accept surrogate motherhood, although certain concerns have been expressed. These concerns are related to: 1. the potential psychological trauma that could arise from the child's relationship with the surrogate mother during pregnancy, 2. legal complications, and 3. the instrumentalization of the female body. These issues highlight the ethical complexities involved in surrogate motherhood, prompting a cautious approach to its practice within these communities. Each of these concerns reflects a broader ethical debate about the implications of surrogate motherhood not only on the individuals directly involved but also on societal norms and values.[25]

[21] Catechism of the Catholic Church. http://www.scborromeo.org/ccc/ccc_toc.htm.
[22] Nnamuchi O, op.cit., pp. 251-272.
[23] Pope Francis: "Απαράδεκτη η παρένθετη μητρότητα (Surrogacy is unacceptable)". https://orthodoxia.info/news/papas-fragkiskos-aparadekti-parenth/.
[24] Deonandan R, op.cit., pp. 269-279.
[25] Nnamuchi O, op.cit., σελ. 251-272.

4. The stance of Islam

Surrogate motherhood in Islam is a complex and often controversial issue that raises a series of theological, ethical, and legal concerns, as it tests the boundaries of Islamic family law. Various views have been expressed regarding this practice and the conditions under which it could be acceptable, both in Sunni and Shia Islam, given that there is no single authority that could definitively pronounce on the matter. As a practice, it is prohibited in most Muslim countries except for Iran, where it is allowed under specific conditions. This diversity in acceptance and regulation reflects the varied interpretations and applications of Islamic principles across different cultural and legal contexts.[26]

The majority of Sunni Islamic scholars believe that surrogate motherhood is haram, meaning it is prohibited. Some argue that obtaining an egg or sperm from a third party and its implantation into a surrogate womb is akin to sharing the marital bed with someone outside of the marriage. Many Muslim scholars view it as a form of unlawful sexual contact (zina). Therefore, it is often discussed in terms of adultery and considered a sinful act. This perspective reflects a strong emphasis on preserving the sanctity of marriage and lineage within Islamic teachings, aligning reproductive actions closely with marital and familial structures as defined by religious law.

In Islam, the foundation is set on preserving family ties and defending the integrity of marriage. According to Sunni scholars, surrogate motherhood confuses the very nature of the family. The mixing of genealogies is seen as contrary to the will of God and therefore is considered both illegal and morally unacceptable. Furthermore, given that the surrogate has a genetic role in the creation of the baby, there is a high likelihood of emotional and legal confrontation between the two women involved. From the process of surrogate motherhood arises the question of which woman should be considered the mother of the child. In Islam, according to Quranic references where the word "Walida" means the person who gives birth to another, the woman who brings the child into the world is considered the mother, not the woman who provides the ovum.[27] Even in cases of polygamy (a husband married to two wives), where an ovum from one wife is fertilized by the husband's sperm and transferred to the womb of the second wife, the pregnant wife carries a "foreign seed," the ovum of the first wife, which is outside the marriage contract that binds the husband and the second wife. The child will belong to the second wife who gave birth to it,

[26] Sujadmiko B, Aji N, Mulyani L, Rasyid S, Meutia, I. Surrogacy in Indonesia: The comparative legality and Islamic perspective. HTS Theological Studies 2023, 79: 1-8. https://dx.doi.org/10.4102/hts.v79i1.8108. Nazari L. Surrogacy in Islam: Is surrogacy haram in Islam?, https://tebmedtourism.com/surrogacy-in-islam/.

[27] Farid S. Why Islam has two ways of looking at surrogacy. https://360info.org/why-islam-has-two-ways-of-looking-at-surrogacy/. Sharmin I, Nordin R, Mohd Nor H, Al-Mahmood A. Ethics of surrogacy: A comparative study of Western secular and islamic bioethics. J IMA 2013, 44:1-5. https://doi.org/10.5915/44-1-5920. Husain F. Reproductive issues from the Islamic perspective. Hum Fertil (Camb) 2000, 3:124-128. https://doi.org/10.1080/1464727002000198831.

although she will not be the biological mother of the child. Therefore, surrogate motherhood, even in this context, is not allowed.[28] However, some views without an absolute prohibition exist, where surrogate motherhood is considered permissible under specific conditions, such as if the surrogate mother is a close relative and if the sperm of the husband and the ovum of the wife are used. In this case, the procedure should be carried out by a female doctor, who, if possible, should be a follower of Islam.[29]

In Shia Islam, there is a more favorable stance towards surrogate motherhood, as Shia scholars utilize the concept of maslaha (public interest) to better understand the ethical dilemmas associated with medically assisted reproduction within Islamic law. Many Shia scholars emphasize avoiding divorce and psychological conflicts. In this context, the majority of Shia Islamic scholars and religious leaders consider surrogate motherhood halal (permissible), provided that it does not involve romantic intercourse and aims to maintain family cohesion. Notably, in 1999, Ayatollah Khamenei, the Supreme Religious Leader in Iran, issued a fatwa (religious decree) permitting surrogate motherhood under certain conditions. He justified his decision by stating that the embryo is created from a married couple and does not involve direct sexual contact, therefore, it cannot be considered adultery. The Supreme Religious Leader of Iran also stated that surrogate motherhood is permissible if performed with the eggs and sperm of the married couple and aims to preserve family cohesion and genealogy. He further noted the importance of transparency in the process and ruled that the surrogate mother should have the right to know the identity of the commissioning parents.[30]

This notable difference in the stance between Shia and Sunni Muslims towards surrogate motherhood stems from differing perceptions of the act of adultery. In Shia thought, adultery is defined as physical sexual contact, not merely the transfer of a fertilized ovum.[31] Additionally, from the Shia perspective, adultery destroys family cohesion, while the "donation" or implantation of a fertilized ovum into the womb of a surrogate mother protects it. Under this interpretation, such a practice is acceptable within Sharia law.[32] The fact that Sunni Islam adopts a different interpretation and almost universally prohibits surrogate motherhood does not mean that instances of "illegal" surrogate motherhood do not occur. For example, in 2013, a young

[28] Hathout H. Islamic perspectives in obstetrics and gynaecology. Alam al-Kutub, Cairo1988.

[29] Chattopadhyay S. Permissibility of Surrogacy in Islamic Law, Chatterjee, Shrabana, Permissibility of Surrogacy in Islamic Law 2020. http://dx.doi.org/10.2139/ssrn.3952492. Niazi S, Islamic Law and the Surrogate Mother. Aref Abu-Rabia, Infertility and Surrogacy in Islamic Society: Socio-Cultural, Psychological, Ethical, and Religious Dilemmas, The Open Psychology Journal 2013, 6: 54-60. Mohsin E. Islamic teachings and surrogate motherhood. Journal for the Study of Religion 1990, 3: 35-45. http://www.jstor.org/stable/24764156.

[30] Sharmin I, Nordin R, Mohd Nor H, Al-Mahmood A, op.cit., σελ. 1-5. Nazari L. Surrogacy in Islam: Is Surrogacy Haram in Islam?. https://tebmedtourism.com/surrogacy-in-islam/. Farid S. Why Islam has two ways of looking at surrogacy. https://360info.org/why-islam-has-two-ways-of-looking-at-surrogacy/.

[31] Nazari L. Surrogacy in Islam: Is Surrogacy Haram in Islam?. https://tebmedtourism.com/surrogacy-in-islam/.

[32] Ibidem.

Egyptian widow named Taghrid gave an interview that caused a stir. Taghrid, while hidden behind a black niqab, disclosed that she rented her womb to a Lebanese couple for 40,000 Egyptian pounds (approximately $2,375). She continued explaining, "I am a widow and have a young son. We have no source of income after the death of my husband. I found a married Muslim couple who had been trying unsuccessfully for 10 years."[33] This case highlights the social and economic pressures that can influence individual decisions regarding surrogate motherhood, even in contexts where the practice is legally and religiously prohibited.

5. The stance of Judaism

The stance of Judaism towards surrogate motherhood varies depending on the interpretation of Jewish law. Generally, surrogate motherhood is considered acceptable, especially when other forms of medically assisted reproduction are not feasible. However, within Judaism, there are significant ethical and legal reservations. The issues mainly concern the identity of the mother, the child's lineage, the relationship between the surrogate and the biological mother of the child, as well as the protection of family cohesion.[34]

The general stance of Judaism on surrogate motherhood is based on God's commandment to the first humans to "αυξάνεσθε και πληθύνεσθε (be fruitful and multiply)." However, for surrogate motherhood to be acceptable, the ovum and sperm must originate from the wife and husband, respectively. From a purely religious perspective, the child is connected to the father who provided the sperm and the woman who brought it into the world.[35] In cases of egg donation, the issue arises as to which woman should be considered the mother of the child—the woman who donated the egg or the surrogate who brings the child into the world. According to Jewish law, the child is related to the woman who brought it into the world, namely the woman who gave birth. Therefore, the majority of scholars tend to support the view that maternity is granted to the surrogate, the woman who gives birth to the child. Another interpretation suggests that a child born in this way has two mothers: the woman who donated the egg and the surrogate.[36] Commissioners, if they have no genetic relation and no physical role in the birth of the child (if the genetic material is not taken from them), are excluded.[37] Recently, there has been a shift in rabbinic thought regarding which woman should be considered the mother in cases of surrogate motherhood, as some researchers argued that the commissioner should be

[33] Abdulmalik A. Taking surrogacy seriously in the Arab world. https://www.arabnews.com/node/1503626.

[34] Schenker JG. Infertility evaluation and treatment according to Jewish law. Eur J Obstet Gynecol Reprod Biol. 1997, 7:113-21. https://doi.org/10.1016/S0301-2115(96)02621-8.

[35] Schenker JG. Human reproduction: Jewish perspectives. Gynecol Endocrinol 2013, 29:945-8.
Besser M. Jewish ethics and surrogacy. Jewish Independent 2017. http://www.jewishindependent.ca/jewish-ethics-and-surrogacy/.

[36] Golinkin D. What does Jewish law have to say about surrogacy? The Schechter Institutes 2012, 7. http://www.schechter.edu/what-does-jewish-law-have-to-say-about-surrogacy/.

[37] Deonandan R, op.cit., pp. 269-279.

considered the mother.[38] It should also be noted that the use of donor sperm is controversial, given the possibility that implanting another man's sperm into a woman's body could constitute adultery, which is strictly prohibited by the Torah. [39]

In Judaism, various opinions have been expressed that support the complete rejection of surrogate motherhood. For instance, Immanuel Jakobovits describes the use of a woman as a "surrogate" as a "repugnant degradation of motherhood and an affront to human dignity." Moshe Tendler opposes both forms of surrogate motherhood, considering them to degrade the dignity of women. Daniel H. Cordis emphasizes that Jewish women should not become surrogate mothers for compensation and that couples of Jewish descent should not seek surrogate mothers. Marc Gellman argues that the sanctity of family life requires a unique husband and a unique wife.[40] Rabbi Jakovitz, as early as 1975, argued that "using a woman as an incubator... for a fee... and then taking away the child she gave birth to is an outrageous degradation of motherhood and an affront to human dignity."[41] Finally, Rabbi Moshe Tendler stated that surrogate motherhood could not be accepted even as a "therapeutic method," as it is wrongly perceived by some as such.[42]

Israeli society is pluralistic, encompassing diverse social groups with different normative traditions. Israel, as a democratic state, follows a liberal approach on many issues, such as the official recognition of single-parent families, while Halachic tradition is promoted with substantial political and legal force. Israel was the first country to regulate issues concerning surrogacy with a specific law in 1996.[43] Under this law, the entire process is strictly controlled and requires the approval of a special state committee case by case. The legislator has imposed several restrictions. For instance, all parties must be adults and legal residents of the Israeli state, surrogacy is offered only to married or otherwise legally recognized heterosexual couples based on medically proven infertility or inability to complete pregnancy, the surrogate mother must be unmarried (divorced or widowed), unless the committee decides otherwise if convinced that the couple could not find an unmarried woman. Further, the surrogate mother may not have a relationship with the prospective parents, the sperm must belong to the prospective father, and the egg must not belong to the surrogate mother (it must come from the prospective mother or a donor), the surrogate mother must share the same religion as the prospective parents

[38] Jotkowitz A. Surrogate Motherhood Revisited: Maternal Identity from a Jewish Perspective. J Relig Health 2011, 50: 835-840. https://doi.org/10.1007/s10943-011-9494-4.

[39] Schenker J. Assisted reproductive practice: Religious perspectives. Reprod Biomed Online 2005, 10: 310-9.

[40] Spitz R. On the use of birth surrogates. https://www.rabbinicalassembly.org/sites/default/files/public/halakhah/teshuvot/19912000/spitz_surrogate.pdf.

[41] Jacobovitz I. Jewish medical ethics: A comparative and historical study of the Jewish religious attitude to medicine and its practice. Bloch Publishers, New York 1975.

[42] Tendler M. Infertility management: Cure or Ill. Sh'ma 1987, 17: 109-10.

[43] The first legal surrogacy contract was drafted by attorney Noel Keane in 1976, and the first compensated surrogacy agreement took place in 1980.Deonandan R, op.cit., pp. 269-279.

unless none of the parties are Jewish, and the surrogate mother is not allowed to receive a salary, however, so-called financial compensation is allowed (this financial arrangement is subject to the approval of the Ministry of Health). In 2011, additional terms/restrictions were articulated, including that the surrogate mother must be between 22 and 38 years old, the age of the commissioners should not exceed the age at which someone can become a parent naturally, the surrogate mother should not undergo more than two embryo transfer procedures, even if they do not result in childbirth, and the surrogate must have at least one child of her own but must not have undergone more than three births.[44]

Israeli legislation is influenced by Jewish religious law, despite differences in content and restrictions. A careful examination of the relevant case law reveals some clear similarities. For instance, the surrogate mother must be unmarried, must not be related to the commissioners, and must share the same religion with them. These restrictions reflect the observance of Jewish law on three main issues, namely religious concerns about: 1. adultery, 2. incest, and 3. religious identity. The first restriction, ideally requiring the surrogate mother to be unmarried, addresses rabbinic concerns about adultery and the status of a child born to a married woman. A child conceived through illicit sexual relations may be deemed a Mamzer and subject to severe social stigma and practical difficulties. Although in vitro fertilization and surrogacy do not involve sexual relations, some rabbis equate it with adultery. The second restriction, prohibiting any connection between the surrogate mother and the commissioners, satisfies religious concerns about incest, that is, marriage or sexual relations between relatives. The third restriction, requiring the surrogate mother and the commissioners to share the same religion, addresses religious concerns about religious identity. According to Jewish law, a child's religion is determined according to the mother's religion, hence the technique of surrogacy could raise significant objections. Since the religion of the surrogate mother has Halakhic significance, the restriction that both parties belong to the same religion circumvents any rabbinic concern regarding the determination of the child's religion.[45]

6. The stance of Hinduism and Buddhism

In Hinduism, surrogacy appears to be permitted, although the issue has not been sufficiently studied yet. Artificial fertilization using the husband's sperm is allowed and not that of an unknown donor, as the child must know their origins.[46] The concept of surrogacy has its roots in Hindu mythology. In the Bhagavata Purana, it is mentioned that Kansh, the king of Mathura, imprisoned his sister Devaki and her

[44] Rimon-Zarfaty N. Parochial Altruism: A Religion-Sensitive Analysis of the Israeli Surrogacy and Egg Donation Legislation. In: Mitra, S., Schicktanz, S., Patel, T. (eds) Cross-Cultural Comparisons on Surrogacy and Egg Donation. Palgrave Macmillan, Cham 2018. https://doi.org/10.1007/978-3-319-78670-4_17.

[45] Ibidem.

[46] Kumar A, Ethical Aspects of Assisted Reproduction. An Indian Viewpoint 2007, 14: 140-142.

husband Vasudeva because a prophecy foretold that their child would kill him. As a result, every time his sister gave birth to a child, he would kill it. After he had killed six children, the gods intervened. They called upon the goddess Yogamaya to transfer the embryo from Devaki's womb to the womb of Rohini, who lived in the village of Gokul. Thus, the child was conceived in the womb of the king's sister but was born through another woman.

Additionally, in Hindu tradition, surrogacy is intertwined with the concept of karma.[47] Infertility is considered a pathology that requires treatment, and thus assisted reproduction and surrogacy are viewed positively.[48] Interestingly, surrogacy is not widely used as an infertility treatment option among Hindus, while many women in India become surrogate mothers for couples from the West.[49]

The stance of Buddhism on the issue of surrogacy is not clear. According to the majority of researchers, none of the sacred texts of Buddhism prohibits assisted reproduction or surrogacy. Compassion is a fundamental concept in Buddhism, and therefore those trying to treat infertility are supported. On the other hand, some researchers have expressed their opposition to the practice of surrogacy, which they base on their belief in karma and reincarnation.[50] Additionally, some equate surrogacy with organ selling and argue that this practice instrumentalizes women and turns them into objects of exploitation for the benefit of others. These positions are contested by other Buddhist researchers who argue that as long as surrogacy is motivated by compassion and not profit, the act is not considered exploitation and is therefore ethically acceptable.[51]

7. Conclusion

Through the examination of the practice of surrogacy at an interreligious level, the existence of both converging and diverging views was observed, which are indicative of the broader degree of moral concerns globally. In all religions, positions were identified that ranged from conditional acceptance of this practice to complete prohibition. It is notable that all religions examine the scientific data and strive to adapt their teachings for the benefit of their congregation. This fact reveals their dynamic nature, which calls them to provide answers to contemporary bioethical issues with the well-being of all involved in mind; in this case, the prospective parents, the surrogate mother, and especially the children. Additionally, in many countries around the world, one or more religions play a significant role in cultural life and influence social ethos and jurisprudence. For this reason, in Israel, the legislature chose to adopt a restrictive approach, aiming to suppress religious objections to the law. Consequently, any action that

[47] Religion and Surrogacy. https://www.montanasurro.com/blog/2018/2/28/religion-surrogacy.
[48] Ibidem.
[49] Nnamuchi O, op.cit., pp. 251-272.
[50] Spirko J. Buddhist Beliefs About Surrogate Mothers. https://classroom.synonym.com/buddhist-beliefs-about-surrogate-mothers-12087675.html. History Channel, Buddhism. https://www.history.com/topics/religion/buddhism.
[51] Nnamuchi O, op.cit., pp. 251-272.

contradicts what is considered moral for society risks causing problems in the established order.

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Ανασκόπηση

Legal Regulation of the Doctor-Patient Relationship in the Czech Republic: Development and Current State, with a Practical Focus on Gynecology and Obstetrics

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Abstract

The article focuses on the development of the relationship between doctor and patient and subsequent legal regulations in the Czech Republic from the beginning of the 20th century to the present. First, it delves into the evolution of the relationship between doctor and patient in the territory of the Czech Republic, providing an overview of important historical events that profoundly influenced the creation of sources and some institutes. Subsequently, it analyzes the current situation in the Czech Republic, subjecting it to a critical evaluation. The author, above all, questions whether the relationship between doctor and patient is truly a partnership and an equal one. The article then addresses persistent inequalities and differences between the rights and obligations of the patient and the doctor. The conclusion acknowledges that, considering the nature of the relationship, it may not be possible to completely eliminate these persistent inequalities. Based on the findings, partial conclusions are formulated, summarizing the individual stages and transformations of this relationship. The analysis of the current state of the relationship between doctor and patient includes a focus on important judicial decisions from practice and how they set limits for the autonomy of the patient's will. In this article, the author primarily concentrates on significant court decisions in the field of gynecology and obstetrics, analyzing how the autonomy of the patient's will is limited in this area in relation to specific situations.

Keywords: Health law; doctor-patient relationship; informed consent; autonomy of the will; gynecology-obstetrics.

Νομική ρύθμιση της σχέσης γιατρού-ασθενούς στην Τσεχική Δημοκρατία: Ανάπτυξη και τρέχουσα κατάσταση, με πρακτική εστίαση στη γυναικολογία και τη μαιευτική

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Περίληψη

Το άρθρο επικεντρώνεται στην ανάπτυξη της σχέσης μεταξύ γιατρού και ασθενή και στις επακόλουθες νομικές ρυθμίσεις στην Τσεχική Δημοκρατία από τις αρχές του 20ού αιώνα μέχρι σήμερα. Αρχικά, εξετάζει την ιστορική εξέλιξη αυτής της σχέσης, σε μια επισκόπηση των σημαντικών γεγονότων που επηρέασαν τη δημιουργία πηγών δικαίου και την ίδρυση ορισμένων ινστιτούτων. Στη συνέχεια, αναλύει την τρέχουσα κατάσταση στην Τσεχική Δημοκρατία, υποβάλλοντας την σε κριτική αξιολόγηση. Το άρθρο περιλαμβάνει αναφορές σε σημαντικές δικαστικές αποφάσεις που θέτουν όρια για την αυτονομία της βούλησης του ασθενούς, κυρίως από τον τομέα της γυναικολογίας και της μαιευτικής. Η συγγραφέας, πάνω απ' όλα, αμφισβητεί εάν η σχέση μεταξύ γιατρού και ασθενούς είναι πραγματικά μια σχέση ισότιμων εταίρων. Στο συμπέρασμα, αναγνωρίζεται ότι, λαμβάνοντας υπόψη τη φύση της σχέσης, είναι δύσκολο να εξαλειφθούν πλήρως αυτές οι ανισότητες.

Λέξεις κλειδιά: Δίκαιο υγείας, σχέση γιατρού-ασθενούς, ενημερωμένη συναίνεση, αυτονομία της βούλησης, γυναικολογία-μαιευτική.

Introduction

The doctor-patient relationship is central to the provision of health care. From the point of view of historical development, this relationship has undergone significant changes. The original unequal position, where the doctor was in a stronger position, turned into a relationship of professional partnership. The reason for the change was, among other things, a change in the primary protected interest. Historically, priority has been given to the protection of the life and health of the individual. It was not expected that the patient would question the doctor's decision and choose a treatment method that would conflict with these interests, or refuse treatment altogether. There were even times when the provision of professional health services was neither common nor available. However, this approach did not respect the will of the patient and his dignity.

The current perception of the doctor-patient relationship is primarily based on communication with the patient and proper instruction. The institute of informed consent is now an integral part of medical procedures. The doctor no longer unilaterally decides on the patient's course of action; instead, they explain the possible procedures in the given case, transferring the choice to the patient. The doctor is no longer the sole authority; they are expected to fully respect the autonomy of the patient's will and the resulting opinion. This expectation holds true in situations where the patient is capable of making decisions about themselves, is conscious, and their mental state allows it, or where their decision does not threaten public health. Is this always fulfilled in practice? Is the doctor-patient relationship truly equal now? Are there still situations where the doctor acts as an authority?

The text aims to provide insight into the doctor-patient relationship, placing it in a historical context, critically evaluating the current state, and highlighting persistent inequalities. Initially, the development of the doctor-patient relationship and its changes in the Czech Republic will be examined. This will include an overview of significant historical events that have profoundly influenced the creation of sources and certain institutes. Additionally, the text will address the guarantee of patients' rights, their manifestations, and the actual fulfillment of these rights in practice. The analysis of the current state of the doctor-patient relationship will also encompass key judicial decisions and how they set limits on the autonomy of the patient's will. The focus of the article will primarily be on crucial court decisions in the field of gynecology and obstetrics. The aim is to analyze how the autonomy of the patient's will is limited in this area, particularly in specific situations.

Based on the above, conclusions will be formulated, and the basic stages of development will be identified. Subsequently, a critical assessment will be conducted to determine whether the current situation in practice represents an equal relationship that can be described as a professional partnership.

1. Historical development of healthcare law in the territory of the Czech Republic

At the beginning of the 20th century in the Czech Republic, the doctor-patient relationship was governed by public law, characterized by inequality. The doctor held an authoritative role, with the main protected interests being life and health. In contrast to the present, where the primary focus is on the autonomy of the patient's will and dignity. During that time, the health status of the population in the Czechoslovak Republic was unsatisfactory due to poor hygienic conditions, lack of food arising from adverse social conditions, and the aftermath of the First World War, especially the high number of post-war invalids.

Although medical care availability improved during the First Republic, legislation in this area remained fragmented, inconsistent, and outdated medical procedures hindered the situation, especially in eastern parts and rural areas.[1] In 1918-1920, the situation came to a dramatic climax during the Spanish flu pandemic.[2] Infectious diseases were on the rise, and the population was also threatened by diseases such as spotted typhus, diphtheria, scarlet fever, whooping cough, tuberculosis, or smallpox. In most cases, these diseases were gradually reduced. Measures, such as compulsory vaccination (e. g. in 1919 against smallpox) or hygiene practices, also contributed to the situation. To address specific issues, specialized institutes were created, such as the Institute for the production of anti-tetanus serum or the Pasteur Institute for the production of rabies vaccine and its treatment.[3]

In the 1930s, the professional public gradually came up with proposals for preventive medicine. Within the framework of Act No. 114/1929 Coll., on the exercise of medical practice (also as „EMP“),[4] the rights and, above all, the duties of a doctor were regulated, such as the obligation to provide first aid (Art. 10 EMP), the right to compensation for the assistance provided (Art. 11 EMP), the obligation of confidentiality (Art. 13 EMP), the procedure for examining and determining a patient's diagnosis (Art. 15 EMP), etc. The law also formulates the way in which medical education can be obtained and the conditions for performing medical practice.

During the period of Nazi occupation from 1939 to 1945, systemic changes occurred and had a significant negative impact on the health sector. The health administration was divided into the Sudetenland part and the protectorate. Public healthcare in the Sudetenland was subject to the locally competent Reich authorities. In the protectorate, the health department was managed by the Ministry of Social and Health Administration. Racial purity supervision and special hereditary health courts (original: *Erbgesundheitsgerichte*) were established.[5] The health conditions of the population worsened during this period. People died due to weakness resulting from hunger and disease, as well as due to physical and psychological torture in concentration camps and inhumane experiments by Nazi doctors. Insufficient medical care also contributed to the mortality, and another portion succumbed to battle injuries. Some Czech doctors were murdered because of their origin, while others went into exile and continued to practice. Increasing obstacles were placed on the education of doctors, and one of the further blows was the closure of universities in 1939.[6] Despite all

[1] Hlaváčková L, Dějiny lékařství v českých zemích, Triton, 2004: 159-161.

[2] Brüssow H, The beginning and ending of a respiratory viral pandemic-lessons from the Spanish flu, Microbial Biotechnology, 2022, 15: 1301-1317.

[3] Hlaváčková L, Dějiny lékařství v českých zemích, Triton, 2004: 162. See also: Lombard M, Pastoret PP, Moulin AM, A brief history of vaccines and vaccination, Revue Scientifique et Technique-Office International des Epizooties, 2007, 26: 29-48. Available at: https://www.researchgate.net/profile/Michel-Lombard/publication/6205699_A_brief_history_of_vaccines_and_vaccination/links/54297ba40cf26120b7b7febe/A-brief-history-of-vaccines-and-vaccination.pdf

[4] Original: *zákon č. 114/1929 Sb., o výkonu lékařské prakse*.

[5] Hlaváčková L, Dějiny lékařství v českých zemích, Triton, 2004: 197-198.

[6] Severa D. Co se stalo 17. listopadu 1939 a co tomu předcházelo? SeznamZprávy. Available at:

these negative influences on a global scale, the field of medicine has advanced significantly. Primarily, this progress was attributed to the United States, both in civilian and military medicine. New treatment methods clandestinely reached the Czech Republic, precisely from the USA (discovery of penicillin) or from England (treatment procedure for burns).[7]

After 1945, the population was weakened, and society had to contend with a number of infectious diseases that had not been eradicated until then. In addition, new diseases were on the rise as a reaction to war and traumatic experiences, mainly cardiovascular, oncological, and psychosomatic diseases.[8]

In 1948, healthcare was centralized and nationalized. It had long been one of the priorities of the communist regime. The right to health protection was enshrined in the constitution of May 9, 1948 (also as „May Constitution“ or „MayC“)[9] within the section on social rights. Article 29 of the May Constitution established a system of public health and social care, intending to provide care for the elderly or persons without care or unfit for work (Art. 29, par. 1 MayC). Specifically, special rights to care during pregnancy and maternity were granted (Art. 29, par. 2 MayC). In the course of the following years, several laws nationalizing healthcare institutions were issued.[10] In Art. 29, par. 3 MayC also refers to other laws, including Act No. 99/1948 Coll., on national insurance.[11] Legislation is gradually being unified through centralization, and so are medical procedures. Laws leading to the systematization of healthcare and even prevention are issued.[12] As a result of these laws, new institutions were created, such as hygienic-epidemiological stations.

A step forward in enabling women to make at least some decisions about their bodies was the adoption of Act No. 68/1957 Coll., on the artificial termination of pregnancy (also as “ATP”).[13] In the introductory provision, it is stated that the law was adopted due to the high risks of harm to the health and lives of women who underwent procedures outside medical facilities, often performed by non-specialists and with fatal consequences occurring frequently (Art. 1 ATP). To ensure the healthy development of the family, women were allowed to undergo the procedure in a medical facility. However, one of the conditions for artificial termination of pregnancy was the request of the woman or her legal representative, which had to be approved by a specially established commission (Art. 3 par. 1 ATP). The commission assessed whether it was possible to comply with the request. The reasons for which the request could be granted included the patient's state of health or other reasons worthy of special consideration (Art. 3 par. 2 ATP). In practice, these cases were very exceptional.

https://www.seznamzpravy.cz/clanek/17-listopad-1939-co-se-stalo-78948.

[7] Hlaváčková L, Dějiny lékařství v českých zemích, Triton, 2004: 195 et seq.

[8] Ibidem: 218 et seq.

[9] Original: *Ústavní zákon č. 150/1948 Sb., Ústava Československé republiky.*

[10] E. g. *zákon č. 185 zestátnění léčebných a ošetřovacích ústavů a o organisaci státní ústavní léčebné péče.*

[11] Original: *zákon č. 99/1948 Sb., o národním pojištění.*

[12] E. g. *zákon č. 103/1951 Sb., o jednotné preventivní a léčebné péči, zákon č. 4/1952 Sb., o hygienické a protiepidemické péči*.

[13] Original: *zákon č. 68/1957 Sb., o umělém přerušení těhotenství.*

Constitutional Act No. 100/1960 Coll., the Constitution of the Czechoslovak Socialist Republic,[14] guarantees the right to health protection in Article 23. Nevertheless, the question remains regarding whether and how this guarantee was actually fulfilled. In 1966, in the Czechoslovak Republic, the relationship between doctors and patients was regulated by Act No. 20/1966 Coll., on People's Health Care[15] (also as „People's Health Care Act" or „PHCA"). This regulation remained unchanged in its original form from 1966 to 1990. During this period, the doctor still acted as an authority towards the patient, and the relationship was so-called paternalistic.

In the 1990s, the law underwent several amendments. In 2001, the Convention on Human Rights and Biomedicine[16] entered into force in the Czech Republic, which had a fundamental impact on the relationship between doctors and patients and foreshadowed the necessary changes to this regulation. The People's Health Care Act was replaced in 2012 by Act No. 89/2012 Coll., the Civil Code[17] (also as „Civil Code" or „CC") which enshrines basic provisions regarding the relationship between doctors and patients, and Act No. 372/2011 Coll., on health services and conditions of their provision (Health Services Act)[18] (also as „Health Services Act" or „HSA"), along with other regulations such as Act No. 373/2011 Coll., on specific health services (also as „SHS"),[19] etc. In connection with the regime change, the healthcare sector was privatized.

It is evident from the above facts that it was not a natural, gradual transformation, but rather the adjustment of the doctor-patient relationship developed only in a democratic society, which was associated with a change of regime. Respecting rights in this area is thus inextricably linked to the general respect for rights in the state.[20]

2. Current situation on the territory of the Czech Republic

2. 1 The relationship between doctor and patient, including its nature and legal regulation

Currently, in the Czech Republic, the patient-doctor relationship is primarily regulated in the private law section, with support found in the Civil Code, specifically in Part Four, Chapter II, Part 9 Health Care (Art. 2636-2651 CC). Now, in most cases, the doctor does not act as an authority, except where it is absolutely necessary, for example, due to the risk of endangering public health.[21] Currently, emphasis is placed on the patient's right to make free decisions about their affairs, body, and the alternatives offered by the treatment. It is the doctor's duty to inform the patient about all alternatives, risks, and potential situations that may arise. The patient's right includes the freedom to decide

[14] Original: *zákon č. 100/1960 Sb., Ústava Československé socialistické republiky*.
[15] Original: *zákonem č. 20/1966 Sb., o péči o zdraví lidu*.
[16] Full name: *Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine*.
[17] Original: *zákon č. 89/2012 Sb., občanský zákoník*.
[18] Original: *zákon č. 372/2011 Sb., o zdravotních službách a podmínkách jejich poskytování (zákon o zdravotních službách).*
[19] Original: *zákon č. 373/2011 Sb., o specifických zdravotních službách.*
[20] Schwarzová A, Vývoj vztahu mezi lékařem a pacientem a navazující právní úpravy od počátku 20. století po současnost, Iurium Scriptum, 2023, 7: 81-94.
[21] Šustek P, Holčapek T, et al, Zdravotnické právo, Wolters Kluwer, 2017.

on the choice of procedure. On the other hand, the doctor also has the right to refuse to perform a chosen procedure (e. g. conscientious objection), and the patient has the obligation to tolerate a certain procedure (e. g. due to the already mentioned risk of endangering public health).

From the perspective of respecting the autonomy of the patient's will, it is generally stated that the relationship between the patient and the doctor is one of partnership and equality. This statement is theoretically valid considering the development and transformation of the doctor-patient relationship. However, this does not imply the absence of inequalities in the doctor-patient relationship.

A contractual relationship, the subject of which is healthcare, represents a service provided to the patient (layman) by the service provider (professional). Therefore, the basic inequality observed is professional inequality. Another inequality is informational. The doctor is always in the role of an expert, and the patient depends on and trusts the information provided by the doctor. In general, the doctor is obligated to familiarize the patient with all information related to the patient's state of health. In specific cases, when all the information would clearly and seriously endanger the patient's health, the doctor may decide not to disclose the information to the patient (the so-called therapeutic privilege). The doctor can provide additional information to the patient, tell only the necessary part, or disclose it to a confidant (Art. 2640 CC).

Other factors that can create inequality and influence the patient's final opinion include pain, fear, or fatigue. Under the burden of the experience of the situation, the patient may make a hasty decision to, for example, alleviate pain quickly. Considering these circumstances, the patient may be more easily influenced. Although the relationship between the doctor and the patient is considered equal in theory, there are significant differences in terms of social psychology, specifically in terms of power and authority, which can impact the autonomy of the patient's will and the final decision.[22] Of course, the health care contract is governed by general principles of obligations or consumer law, such as the principle of protecting the weaker party. Therefore, the patient is considered the weaker party and is accordingly protected. In cases of uncertainty in the relationship between the doctor and the patient, the decision is made in favor of the patient.[23]

2. 2 Informed consent

One of the essential parts of the health care contract is the patient's informed consent (Art. 2642, par. 1 CC). When the doctor becomes familiar with the patient's condition, a decision is made on the next course of action. The doctor cannot proceed with this procedure without the patient's consent, unless the law provides otherwise (Art. 2642, par. 1 CC). Informed consent is required for each procedure. Specific exceptions, allowing the provision of health services without the patient's consent, are listed in the Health Services Act. These include situations, for example, where the patient's state of health necessitates urgent care and simultaneously prevents the expression of consent (Art. 38,

[22] Kipnis D, Does power corrupt? Journal of Personality and Social Psychology, 1972, 24: 33-41.
[23] Šustek P, Holčapek T, Informovaný souhlas: Teorie a praxe informovaného souhlasu ve zdravotnictví, Aspi, 2007: 50-51.

par. 1, lett. c) HSA). Furthermore, in situations such as an immediate and serious threat posed by the patient to himself or his surroundings (Art. 38, par. 1, lett. b) HSA), or if the patient has been ordered to be isolated or quarantined (Art. 38, par. 1, lett. a), point 2. HSA), or protective treatment in the form of inpatient care imposed by a final court decision (Art. 38, par. 1, lett. a), point 1. HSA), etc.

If the patient consents, the consent must be informed and freely given. The doctor is obliged to instruct the patient in a proper and comprehensible manner. As part of the instruction, the doctor must clearly explain to the patient the intended procedure, possible risks, and consequences (Art. 2638, par. 1 CC). The doctor must ensure that the patient has understood the information communicated to him (Art. 2639, par. 1 CC). Only subsequently can the patient give consent to the act, unless the law stipulates that consent is not required in the given case (Art. 2642, par. 1 CC). The above conditions can be conveyed verbally or in writing, as required. The extent of instruction will also depend on the circumstances. As stated above, if the doctor assesses that the instruction is redundant under the given circumstances or could endanger or worsen the patient's health, he can modify the scope and provide adequate instruction or perform it additionally (Art. 2640 CC).

In the event that the patient refuses to give consent, the provider of health services may require written confirmation (Art. 2642, par. 1 CC). However, the health care contract does not expire by refusing an individual act within the framework of care. The obligation as a whole is canceled only if the patient expressly refuses health care (Art. 2651 CC).

2. 3 Limits of autonomy of the patient's will in healthcare law (with a focus on the field of gynecology and obstetrics)

Respecting the autonomy of the patient's will and their decisions is also related to the principle of protecting the inviolability of the patient. However, concerning the monitored protected interest, the rights of the patient may be limited in some situations. In such cases, the doctor performs the act against the patient's will. The Constitutional Court, in its judgment of May 18, 2001, no. IV. ÚS 639/2000, states that in cases where it is necessary to perform certain medical procedures or examinations without the express consent of the patient, it is always necessary to proceed with maximum restraint. A doctor should act in accordance with the principle of free decision-making in matters of personal health care, which arises from the constitutional principle of the inviolability of a person's integrity. And he adds that a diagnosis cannot be more than a right.

In this chapter, I will present some interesting cases that have occurred in practice. These represent significant decisions made by Czech courts, establishing limitations on the autonomy of the patient's will, particularly in the field of gynecology and obstetrics. The discussion will also highlight situations in which granting the patient's informed consent is excluded.

2. 3. 1 Conflict between the rights of the mother and those of the unborn child

In jurisprudence, the conflict between the rights of the mother and those of the unborn child is typically mentioned in relation to the limitation of the patient's rights. It is applicable in cases where the life and health of the unborn child are immediately threatened, allowing for the limitation of the mother's rights if actions are taken that are adequate to the purpose and protection of the life and health of the unborn child.[24]

In a situation where the patient is, for example, a child unable to give consent on their own, their legal representative can give

[24] E. g. Decision of the Constitutional Court, March 16, 2021, no. III. ÚS 2480/20.

what is known as proxy consent. Substitute consent can only be granted for a procedure that will directly benefit the patient.[25] In practice, on the contrary, it may also happen that legal representatives do not agree with the procedure proposed by the doctor. In its judgment of August 20, 2004, the Constitutional Court, no. III. ÚS 459/03, dealt with the admissibility of interference with parental rights for the purpose of protecting the health and life of a minor child. This was a situation where the child was diagnosed with a highly malignant cancer. The proposed treatment included chemotherapy and a blood transfusion. Due to their religious beliefs (Jehovah's Witnesses), the parents rejected the proposed *lege artis* treatment and demanded alternative treatment, mainly consisting of pain relief. It should be noted that none of the alternative options in this case were able to eliminate the causes of the disease other than the treatment suggested by the doctor. In this case, the Constitutional Court expressed the opinion that parents cannot be allowed to take measures harmful to the health or development of the child.[26]

2. 3. 2 The mother's right to release the placenta

Another issue concerning rights in the relationship between doctor and patient is the patient's right to decide about their body, its parts, and how they should be disposed of. The Constitutional Court of the Czech Republic, in its judgment of March 16, 2021, no. III. ÚS 2480/20, dealt with a complaint in which the complainant stated, among other things, her right to the inviolability of the person and privacy according to Art. 7, par. 1 Charter of Fundamental Rights and Freedoms[27] (also as „ChFRF“), as well as the right to protection against unauthorized interference in private and family life according to Art. 10, par. 2 ChFRF. The complainant received medical care in the field of obstetrics and gynecology at a medical facility. Following the care, the applicant requested the release of the placenta. The complainant believes that she has the right to have the placenta released, unless demonstrable reasons aimed at protecting public health prevent it. As the medical facility refused to release the placenta, she asserted that her personal rights were violated and demanded compensation for the non-pecuniary damage caused during the provision of medical services. The general courts unanimously concluded that the medical facility acted *de lege artis* in pursuing the goal of protecting the health of the child and the mother. The complainant was at risk of infection after the amniotic fluid was drained, and a blood test confirmed the presence of infection. Consequently, she was administered antibiotics. Due to the possibility of pathological changes in the placenta and its potential defectiveness, the decision was made not to release it. Objectively, no non-property damage occurred.

The Constitutional Court did not conclude that the applicant's fundamental rights were affected, as it was not possible to rule out the possibility that the placenta was already in a

[25] Povolná M. Komentář k ustanovení § 2642. In: Petrov J. et al. Občanský zákoník. Komentář. 2nd updated edition. C. H. Beck, Praha, 2023.

[26] Decision of the Constitutional Court, August 20, 2004, no. III. ÚS 459/03.

[27] Original: *Usnesení č. 2/1993 Sb., usnesení předsednictva České národní rady o vyhlášení LISTINY ZÁKLADNÍCH PRÁV A SVOBOD jako součástí ústavního pořádku České republiky*.

pathological state. Thus, it arrived at the same result as the general courts and concurred with the denial of the delivery of the placenta. However, it states that the denial of the right to release the placenta in general, without further ado, cannot be considered constitutionally compliant. In the event that there is no known reason indicating that a person's health should be at risk, health service providers are obliged to release the placenta to the mother upon request. The Constitutional Court further justifies this by emphasizing that the placenta is a separate part from the patient's body, and the decision of how such a body part should be disposed of falls within the scope of a person's freedom to decide how to live according to their own way. It is not up to medical facilities or courts to evaluate the motivation of women giving birth.

In its justification of the decision, the Constitutional Court states that the autonomy of the individual's will, both mentally and physically, must be respected. It emphasizes that the state has only limited possibilities to interfere in an individual's decision-making or limit their rights. The reasons for such restrictions may include the protection of the rights of other persons or other constitutionally protected assets. The recognition of the legal subjectivity of the individual and their will is manifested through free and informed consent. Consequently, the patient can express their will by disapproving and refusing a procedure, even though the consequences could be negative. This underscores the current concept of the relationship between doctor and patient, which respects and protects human dignity and freedom (Art. 3, par. 1 CC) and acknowledges the right of everyone to live according to their own wishes (Art. 81, par. 1 CC).

In relation to the handling of the placenta (and parts of the body), it addresses the obligations of the medical facility according to Art. 26 HSA, including the options for preservation and use, as well as the obligation to cremate the placenta. Regarding the cremation of the placenta, it argues that a purely grammatical interpretation of this provision is incorrect. The obligation to incinerate the placenta comes into consideration only when the patient does not request the delivery of the placenta, and at the same time, when delivery is not prevented by other serious reasons. Cremation of the placenta is a solution for a situation in which the patient is not interested in the placenta, and the hospital has to dispose of it. It emphasizes that proportionate interference with the patient's right is possible if there are serious reasons for which the release of the placenta by the medical facility is inadmissible, as such a procedure is contrary to the public interest in health protection.

2. 3. 3 Artificial insemination with the germ cells of the deceased husband

In this case, the Supreme Court of the Czech Republic ruled in its judgment of February 21, 2018, no. 21 Cdo 4020/2017, regarding the appeal of a female reproductive clinic patient. The Supreme Court investigated the question of whether the failure to fulfill the obligation to complete the process of artificial insemination with the germ cells of the deceased husband is capable of interfering with the patient's right to family life.

The patient sought to be legally and artificially inseminated using her germ cells and the cryopreserved sperm of her late husband. The husband died on June 16, 2015. On June 26, 2014, he signed an informed consent for sperm cryopreservation before infertility treatment and assisted reproduction methods. He never revoked this consent. On December 15, 2014, the patient and her husband signed an informed consent for infertility treatment using the in vitro fertilization method, consented to the thawing and use of sperm before infertility treatment using assisted reproduction methods, and on the same day, they also signed an informed consent for intracytoplasmic sperm injection. Subsequently, the patient was no longer given hormonal injections because her husband died, and her mental state after her husband's death did not allow the artificial insemination process to continue. After some time, she again demanded to continue the process of artificial insemination. However, the clinic refused to accommodate the patient due to the

absence of the husband's valid consent. The clinic stated that Art. 6 SHS prevents the completion of the artificial insemination process. According to this provision, artificial insemination can only be carried out if the request of the infertile couple requesting artificial insemination is not older than 6 months. In addition, this provision emphasizes the informed consent of the future parental couple, as it aims to treat the infertility of a man and a woman, not an individual. In this case, informed consent does not replace the previously expressed consent of the deceased spouse, and artificial insemination cannot be performed on its basis. The patient disagrees with this and believes that the clinic acts in violation of the principle of pacta sunt servanda but also denies the plaintiff her right to private and family life.

The Supreme Court also determined that the deceased's parents, who were heirs in addition to the patient, would have consented to the artificial insemination procedure. Furthermore, it is important to note that part of the informed consent included the instruction that sperm storage concludes in the event of the man's death, unless otherwise specified. Details about proposed methods, procedures, embryo storage, information on parentage determination, expected financial costs, and the storage period are integral components of the education provided to the infertile couple (Art. 8, par. 1 SHS). Subsequently, the infertile couple provides written consent for assisted reproduction, and this written consent must be obtained before each artificial insemination (Art. 8, par. 2 SHS).

The Supreme Court maintains the position that the failure to complete the process of artificial insemination with the reproductive cells of the deceased husband is not capable of interfering with the patient's right to family life, as it objectively does not exist. Nevertheless, it may represent an interference with the right to private life, given the close connection between the patient's desire and her husband's to start a family, with their actions being aimed at this goal. Artificial insemination can be pursued if it is unlikely or improbable for a woman to become pregnant naturally, and other treatment methods for her or her partner would not, or with a high degree of probability, lead to pregnancy. The court further notes that the husband's consent was limited to joint artificial insemination, not a blanket consent to the creation of embryos.

The Supreme Court further asserts that the rationale behind establishing the 6 month period is rooted in the child's right to know his parents, as outlined in Art. 7 of the Convention on the Rights of the Child.[28] Consequently, in cases of artificial insemination, it is stipulated that the child should be born into a complete family. The crucial moment determining the status of a child born from artificial insemination is the re-consent of the father. Artificial insemination cannot proceed without the consent of the man, and after his withdrawal, against the will of the husband, mother, or partner, or after his death.

The Supreme Court further asserts that, according to the explanatory report to the law, it can be inferred that artificial insemination is possible only *inter vivos* (between the living). Simultaneously, the condition of treating the couple's infertility must be fulfilled. This inference is supported by the allowance of artificial insemination for a woman in her fertile age. It is evident from the above that after the death of the man who forms the infertile couple, it is no longer possible to refer to them as an infertile couple or to provide treatment. In this case, even doubts arise as to whether the man would have still consented to artificial insemination after his death, given that the informed consent for the preservation of biological material also included a provision

[28] Original: *Sdělení č. 104/1991 Sb., sdělení federálního ministerstva zahraničních věcí o sjednání Úmluvy o právech dítěte*.

for destruction in the event of death. The Supreme Court concludes that, in this case, the assisted reproduction clinic did not make a mistake. A reproductive health care provider is not obliged to complete artificial insemination by combining a patient's germ cell with her deceased husband's cryopreserved sperm.

2. 3. 4 Situations in which the granting of informed consent is excluded

As part of the introductory provisions of the Civil Code, it is formulated that everyone has the right to the protection of life and health, as well as freedom, honor, dignity, and privacy (Art. 3, par. 2, lett. a) CC). In connection with this provision, it is necessary to recall Art. 19, par. 2 CC, which states that the natural rights associated with a person's personality cannot be alienated and cannot be waived. If this happens, it is not taken into account (Art. 19, par. 2 CC). This is a very important rule for the field of health law and research. In general, you cannot give consent to another to injure or kill another. In the field of healthcare, however, interference with bodily integrity protects protected interests, health, and life, and this is a procedure in accordance with the law. The Civil Code, for these cases, enshrines a rule that confirms this and says that, apart from the cases established by law, no one may intervene in the integrity of another person without his consent given with knowledge of the nature of the intervention and its possible consequences. If one consents to be seriously harmed, it is disregarded; this does not apply if the intervention is necessary under all circumstances in the interest of the life or health of the person concerned (Art. 93, par. 1 CC).

2. 4 Public law limits within the doctor-patient relationship

The legislator emphasizes the change that the relationship between doctor and patient has undergone (as early as the 1990s) and its private law nature.[29] The explanatory memorandum to this, clarifies that this private law anchoring does not negate the impact of public law regulations on this relationship.[30] One example is the adjustment of health insurance, for instance.[31] In addition, physicians may face criminal liability in cases of malpractice. Currently, there exists an expert consensus on the correct or appropriate treatment procedure for doctors, known as the *lege artis* procedure. This obligation is generally regulated in Art. 2643 par. 1 CC and in Art. 45, par. 1 HSA. The term *lege artis* is not explicitly defined by law. Essentially, it represents the most optimal solution, considering crucial circumstances and respecting the autonomy of the patient's will. Non-compliance with the *lege artis* procedure or potential misconduct can be addressed not only through disciplinary proceedings and at the civil level but also within the realm of criminal prosecution. Thus, even though it involves a private law relationship, the intertwined public law aspects cannot be overlooked.

In connection with public law, it is essential to highlight the obligations that a doctor has, irrespective of the patient's will, especially concerning the handling of information obtained from and about the patient. Besides the selection of a treatment procedure, patients

[29] Explanatory note to the Civil Code.
[30] Ibidem.
[31] Ministerstvo zdravotnictví ČR, Veřejné zdravotní pojištění, Available at: https://www.mzcr.cz/verejne-zdravotni-pojisteni-2/.

have the right to decide whether and to whom information about their person and health condition will be disclosed. In this context, doctors are bound by a duty of confidentiality, and any violation of this duty can result in criminal liability. The doctor committing the criminal act of unauthorized handling of personal data pursuant to Art. 180, par. 2 of the Act No. 40/2009 Coll., Criminal Code.

Conversely, doctors are obligated to report facts they learn in the course of their work, as required by HSA or other legal regulations (Art. 51, par. 2, lett. c) HSA). Additionally, they must provide information for the needs of criminal proceedings either voluntarily or upon request (Art. 51, par. 2, lett. d) HSA). When obstructing the notification of a criminal offense or disclosure of patient information, or when releasing a patient's medical documentation for criminal proceedings, doctors function as authorities and must act in accordance with their imposed duties. Failure to do so may result in criminal sanctions.

The field of health law is highly specific, as it amalgamates various legal and scientific branches. This specificity is evident in the extensive framework of standard-setting within the realm of health care, encompassing over a thousand statutory and by-law sources, including ethical codes.

Discussion

It is evident that in the Czech Republic, there hasn't been a gradual development in healthcare law, but rather a systemic change has taken place. The development in the territory of the Czech Republic from the beginning of the 20th century to the present day can be divided into several basic stages. The first stage involves the separation of the department of public health, leading to the creation of a separate ministry. During this time, legislation became fragmented, reacting to problems that had already arisen and addressing the poor hygienic conditions of the population and epidemic situations. Another significant issue during this period was the availability of health care. Although efforts were made for systemic changes, the period of Nazi occupation fundamentally affected the planned changes.

The second stage involves the centralization and nationalization of healthcare. During this period, the relationship between doctor and patient still maintains a public law nature, with the doctor acting as an authority. The right to health protection is formally enshrined in the constitution, and care becomes more accessible through the creation of a system of public and social care. However, the autonomy of the patient's will is limited by the (dis)respect of rights in society. For instance, patients are legally allowed to undergo an artificial termination of pregnancy upon request, but the reasonability of the request is decided by a commission established for this purpose. A unified specialized legal regulation is created - the Act on People's Health Care. Although there are already international-level documents guaranteeing patients the right to decide for themselves based on informed consent, these procedures are not consistently followed.

The third stage involves the transformation of the legal nature of the relationship between the doctor and the patient, anchoring it within the private law framework. In the first two stages, the focus was on addressing the availability and systematization of healthcare provision. Only in the third stage can we truly talk about the relationship between the doctor and patient. The doctor-patient relationship is now perceived as equal, with an emphasis on communication with the patient. The patient is free to decide, and their will is respected. In general, prior informed consent of the patient is always required for the provision of health services.

The theory describes the current relationship between the doctor and the patient as an equal partnership, often referred to as a professional partnership. While this statement is generally valid, emphasizing the respect for the autonomy of the patient's will in contrast to earlier times, the specificity of this relationship introduces complexities. Despite the notion of equality in the doctor-patient relationship, various inequalities can emerge in specific situations, primarily in terms of professional and informational aspects. In most cases, the

patient is a layman making decisions based on information provided by the doctor. The doctor is obligated to share all crucial information transparently, ensuring that the patient understands the message without feeling overwhelmed. However, the doctor retains significant influence over the communication's extent, deciding, in justified cases, to withhold certain information. Conversely, the patient is also obliged to truthfully communicate all relevant facts that could impact proposed procedures. Mutual trust stands as a crucial component in the doctor-patient relationship.

Another inequality arises from the fact that the patient actively seeks out a doctor and visits the doctor in their environment. Typically, patients consult doctors when they already have a health issue. Given that the patient is not an expert and relies on the information provided by the doctor, decisions are often made under the influence of their current condition. Factors such as pain, fear, shame, anxiety, fatigue, may affect the decision-making process. Due to these considerations, the patient is regarded as the weaker party and is therefore entitled to protection.

Significant differences are evident in the rights and obligations of the parties involved in this relationship. The doctor is bound by a comprehensive set of legal regulations that impose various obligations. Consequently, there are situations where the doctor is obligated to act, irrespective of the patient's wishes. Examples include instances where a doctor may act against the mother's will to protect the rights of an unborn child whose life and health are at risk. In cases involving child patients, the doctor is obliged to intervene if the legal representatives take actions that may be harmful to the child's health or development, among other scenarios.

In the field of obstetrics and gynecology, the mother's right to handling the placenta may be further restricted. Generally, the patient has the right to decide how the severed body part should be disposed of, unless otherwise specified. However, if there is a known reason that the separated part of the body could endanger the health of a person, it cannot be issued. Medical facilities in the Czech Republic are obliged to respect the autonomy of the patient's will and release the placenta. Mothers can only be restricted in their rights if the delivery of the placenta would be contrary to the public interest in health protection.

Another case that may arise in practice is the patient's request to complete artificial insemination with the germ cells of her deceased partner. This is a very specific and borderline situation that was resolved in the Czech Republic in 2018. Czech law allows assisted reproduction only as a means of treating an infertile couple (a man and a woman). Artificial insemination cannot be carried out without the consent of the man, and after the withdrawal of consent, against the will of the husband, mother, or partner, or after his death. Although the patient felt that her rights had been violated, the court expressed a clear opinion that such a procedure is not possible in the Czech Republic. In this case, limiting the autonomy of the patient's will, who was requesting artificial insemination with the germ cells of her deceased husband, protects the rights of other persons, namely the rights of the deceased spouse and the unborn child.

Although the nature of the relationship between the doctor is private law, it is still limited by public law norms that may interfere with it. In a situation where a patient is suffering from a highly contagious disease, it is the doctor's duty not only to treat the patient but also to prevent the spread of the disease. The patient may be placed in quarantine despite disagreement. From the viewpoint of communicating information, a situation may arise in practice where the doctor is obliged to communicate the discovered information to the relevant institutions and authorities regardless of the patient's consent. In addition to the reporting obligation, the doctor may, in justified cases, release the patient's entire medical records to law enforcement authorities for the purposes of criminal proceedings. The rights and obligations of a doctor may also result from professional regulations and ethical standards. In the event of a doctor's misconduct, which may result from a wrongly

chosen procedure, disregarding the patient's will, breach of confidentiality, failure to report information to the competent authority, violation of hygiene standards and preventive measures, etc., the doctor is responsible for his actions and may face different types of sanctions (private law, labor law, disciplinary, criminal). In contrast, the patient does not have these obligations and is protected. In cases of doubt, the decision is made in favor of the patient. I believe that the mentioned inequalities regarding responsibility in the relationship between doctor and patient may partly contribute to establishing the position of the doctor as an authority.

In addition to the reasons mentioned above, inequalities can also be observed resulting from research in the field of social psychology. The research results highlight significant differences in power and authority within the doctor-patient relationship. Among other things, this asymmetry can consciously and unconsciously influence the individual decisions of the patient.

Personally, I believe that the above-mentioned inequalities are very difficult to eliminate. Considering the nature of the relationship, the protected interests, and the potential consequences that may arise in the event of a mistake, it is logical that doctors often prefer to proceed cautiously. This cautious approach, however, in some situations, may result in a lack of respect for the patient's will. Structured education for doctors in this area could improve the situation, addressing both the rights and obligations in relation to their person and the performance of their profession, as well as the rights and obligations of patients. Similarly, positive benefits would arise from educating patients, with a focus on understanding the differences and positions of individual subjects.

Patients would become more active participants in their own care and could play an increasingly involved role in the decision-making process about their body and health. In the future, the relationship between doctor and patient could evolve into more of a professional partnership, with the doctor serving as a guide to health care. However, this transition may not be without exceptions, as the doctor's statements from a position of authority could still persist in certain situations.

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