

Legal Safeguards for Medical Consumers in India: An Analysis under BNS, BSS, BNSS, and the Drugs and Cosmetics Act, 1940

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ABSTRACT

Three new laws, Bharatiya Nyaya Sanhita, 2023, (BNS) Bharatiya Nagarik Suraksha Sanhita, 2023, (BNSS) and Bharatiya Sakshya Adhinyam, 2023 (BSA) have been enacted and introduced to replace the laws of colonial era, i.e., Indian Penal Code, 1860, Code of Criminal Procedure, 1973, and Indian Evidence Act, 1872. After the introduction of these three laws, numerous provisions related to them attracted the attention of the general public, and debates and discussions began on various forums. Considering the changes in these three important laws related to the general public issues and governance, it is essential to assess the impact of these laws on medical consumers, who are often subjected to negligence and mismanagement. This article aims to analyse the specific provisions of these three laws, along with the Drugs and Cosmetics Act, 1940, supported by news reports, articles, and case laws, to determine how an aware citizen can protect their own life and the lives of their loved ones while also taking necessary legal action. An attempt has been made to examine how the basic knowledge and understanding of the relevant Sections of BNS, BNSS, BSS, and the Drugs & Cosmetics Act are required for the medical consumers in the era of commercialisation, when the Registered Medical Professionals (RMPs) and corporate hospitals are ignoring the public well-being at the cost of their pecuniary benefits. The article concludes that a knowledgeable medical consumer can ensure civil, criminal, and regulatory accountability in the cases of medical negligence and related cases of medical mismanagement.

Keywords: Medical Consumers, Medical Negligence, Bharatiya Nyaya Sanhita (BNS), Bharatiya Nagarik Suraksha Sanhita (BNSS), Bharatiya Sakshya Adhinyam (BSA).

Introduction

In the present times, due to the commercialization of healthcare sector and money mindedness of corporate hospitals and the health service providers, we have often witnessed media reporting the news relating to medical negligence cases and hence, the general public and academicians are supposed to remain informed and aware with respect to their rights because ignorance of legal provisions as well as specific facts pertaining to the case creates a hindrance for all those who want to proceed to fight for their legal rights, hence, victims of medical negligence as well as the legal experts must understand and apply the relevant provisions of the act to apply in a specific cases of medical mismanagements.

Medical malpractice and negligence are assumed to occur when a health service provider fails to apply reasonable skill in treating a patient, breaches the duty of care, and fails to exercise due diligence and care, resulting in casualty, financial losses, mental agony, and even death of the medical consumer. The issue of medical malpractice may be diverse ranging from false documentation, delay or non-issuance of medical records, improper treatment, not following the standard medical protocols,

infecting the patient, not maintaining the medical records or deliberately not providing the same to the patient, negligence in surgery, surgical procedure without taking proper informed consent, taking consent on a blank paper, overcharging for medicine/tests or other services, violence or discrimination in the hospital, employment of quacks in a hospital, extracting money by showing artificial emergency, etc. Often, a legal battle between a medical consumer and the medical professionals and corporate hospitals are considered as a '*battle between unequals*' because every test, medical report, documents, etc. is originated through the medical service providers and they are always in a position to write or change the documents as per their need and convenience, secondly, if a case of medical negligence is filed then the matter is referred to the doctors or hospitals for the obvious reason of their expertise. But, in most cases, either they give a clean chit directly or, quoting multiple medical jargons and literature, they prefer to give the benefit of doubt to the doctors.

This article examines some of the key provisions of the newly enacted BNS, BSA, and BNSS, as well as the Drugs and Cosmetics Act, 1940. But, before coming to the discussion of the relevant section, it is required to understand that BNS defines the offences and their punishments (the "substantive law"), while the BSA governs the "procedural law", i.e., it deals with admissibility, relevancy, and weight of evidence in the court proceedings. Therefore, for an aggrieved medical consumer, the BSS plays a pivotal role in proving their case, while the BSA provides the legal framework for presenting the matter in court. Knowledge of BNSS is critical for an aggrieved medical consumer, as it outlines the process of initiating criminal proceedings and educates them regarding the investigation process, along with the knowledge of procedural safeguards that are in place.

Literature Review

The introduction of a new law or the replacement of an old one with a new one is always considered a landmark step for any society. The present article not only deals with three new laws, namely, BNS, BSA, and BNSS, but also extends its scope to the Drugs and Cosmetics Act, 1940. References to the CPA 2019 and the NMC Act, 2019, have been made as per the requirements. As the three laws were enacted in 2023, there is currently no direct work among these new laws. Additionally, there is a lack of extensive academic literature that covers the other laws addressed in this research work. The author is utilising bare acts, newspaper editorials, think-tank publications, and legal blogs for an extensive study and systematic examination of the statutes, the implications of the changed laws, and to address the research gap on the present topic.

Research Methodology

Being recently enacted, there is a paucity of academic literature assessing the impact of the three laws primarily covered in the article. The available literature primarily focuses on the repealed laws and their historical context. The present study adopts a '*doctrinal research approach*' to examine the new laws. It will also cover secondary sources, such as landmark court judgments, news reports, and credible online sources, to analyse, highlight, and develop a clear understanding of the issues and their practical implications.

Objectives of the Study

The primary objective of this article is to systematically examine the statutes and find implications of the changed laws. The purpose of the article is not to compare the old act and its provisions with the new act; the objective is to educate the medical consumers and victims of medical negligence about the provisions of the recently enacted acts so that they may take adequate medical safeguards in the case of need.

Landmark Judgements in the Cases of Medical Negligence

The society in general gives high value and regard to the medical professionals, and they are expected to exercise a reasonable degree of care and professional skill, which is ordinarily expected from a Registered Medical Practitioner (RMP) under similar circumstances. However, in practice, medical consumers, i.e., patients, are often grappling with issues stemming from medical negligence impacting their physical, mental, and financial well-being. These issues are often considered to be the result of commercialisation and corporatisation of the health care sector, as well as a wrong notion of the Indian society, which considers doctors as 'God' instead of considering them as a 'Service Provider'. A kind of 'legal immunity' granted to the RMPs, along with the inherent power imbalance between healthcare service providers and patients, and the lack of transparency in the healthcare system, are also considered some of the reasons for the rising number of medical negligence cases in India.

At the time of examining a complaint of medical negligence, the court examines whether the medical professionals failed in performing their 'duty of care' and if it is established that the 'breach of duty' occurred in the given case, which resulted in 'injury or harm', then the case is deemed fit for adjudication in favour of the complainant. Some landmark judgments involving medical negligence cases can be helpful in understanding the issue of medical negligence and what is required to hold a healthcare service provider criminally liable.

To understand whether an adverse outcome of a medical treatment can be categorised as medical negligence or not, the landmark judgements pronounced by the Hon'ble Supreme Court, in *Jacob Mathew Vs. State of Punjab & Anr (2005)*, may be referred to. This judgement also directs for medical opinion from a government doctor before taking any action against the medical professional in the alleged cases of medical negligence. The order says, "*The investigating officer should, before proceeding against the doctor accused of rash or negligent act or omission, obtain an independent and competent medical opinion preferably from a doctor in government service qualified in that branch of medical practice who can normally be expected to give an impartial and unbiased opinion applying Bolam's test to the facts collected in the investigation. A doctor accused of rashness or negligence, may not be arrested in a routine manner (simply because a charge has been levelled against him). Unless his arrest is necessary for furthering the investigation or for collecting evidence or unless the investigation officer feels satisfied that the doctor proceeded against would not make himself available to face the prosecution unless arrested, the arrest may be withheld.*" [1]

Often it has been observed that, law enforcement agencies favour the 'mighty' medical service providers and the complaints of medical negligence matters keep waiting for years. A pertinent news reported by Rema Nagarajan (2024) in *The Times of India*, highlights the significant gaps in healthcare accountability in India, and it concludes everything in just one sentence in the opening of the news itself, i.e., "It took a 15-year battle for a lower court to take cognisance in a case of death due to alleged medical negligence". [2]

Some of the court decisions of Pre BNS era seem to be favouring the RMPs in such a manner that it makes almost impossible for a victim of medical negligence to press for criminal prosecution of RMP. *Dr. Suresh Gupta Vs. Govt. of NCT of Delhi (2004)* [3] is a pivotal case in which trial court ordered for criminal proceedings against accused RMP, Dr. Suresh Gupta because of whose negligence a patient died during a nasal deformity corrective surgery; on appeal Delhi High Court refused to quash the criminal proceedings against him. The matter finally reached the Hon. Supreme court which quashed criminal proceedings against the RMP and held that in the cases involving medical negligence against an RMP, the standard of negligence must be "so high that it can be described as 'gross negligence' or 'recklessness'." It was further established that 'simple lack of care or an error of judgment' cannot create a ground for criminal charges. The order reads that, "*To convict, therefore, a doctor, the prosecution has to come out with a case of a high degree of negligence on the part of the doctor. A mere lack of proper care, precaution, and attention, or inadvertence might create civil liability, but not a criminal one. The courts have, therefore, always insisted in the case of an alleged criminal offence against a doctor causing the death of his patient during treatment, that the act complained against the doctor must show negligence or rashness of such a higher degree as to indicate a mental state which can be described as totally apathetic towards the patient. Such gross negligence alone is punishable.*"

It is surprising to note that not a single RMP has been convicted under the IPC in the last 60 years. Even after finding doctors grossly negligent, they were left unpunished, with some receiving only strict comments or warnings. However, one reference of 7 years' rigorous imprisonment under the IPC with respect to a medical professional is available. A close examination of the matter, however, creates some confusion regarding the concerned medical professional, who claimed to be a compounder and not a doctor. In this case, the medical professional Riyazuddin was found grossly negligent and was held criminally responsible for his act, which caused the death of Ms Sushmita, a pregnant woman, in the year 2006. (*Riyazuddin vs. State (NCT of Delhi), 2015*). [4] The order of the Hon. Delhi High Court was challenged in the Hon. Supreme Court, where the previous order was upheld. This news was widely reported in national media (Anand, 2015). Apart from this, no reference to any Criminal prosecution of an RMP is available in any of the medical negligence cases. [5]

Challenges for Medical Consumers (beyond CPA 2019)

To proceed with the criminal aspect of medical negligence, the litigant must be very specific about proving "gross negligence" in the treatment of the patient; hence, a very high standard has been

set for determining gross or reckless negligence. It is pertinent to note that minor errors or mistakes or errors of judgment resulting in adverse outcomes do not automatically attract criminal liability; thus, the aggrieved patients must have strong prima facie evidence to proceed with the case. In such cases, expert medical opinion is sought 'preferably from government doctors' as per *Jacob Mathew v. State of Punjab*, (2005) [1]. Considering the complexities of the matter involved, often Courts rely on the reports of 'medical boards or experts', which is generally a time-consuming process. The burden of proving criminal negligence generally lies with the prosecution, which requires clear evidence that is often impossible for a layperson to obtain without a deep understanding of the matter, along with assistance from reliable medical experts. Often, medical consumers face practical challenges in acquiring the complete medical records from hospitals in a timely manner without the intervention of the court and law enforcement agencies; however, knowledge of the provision with regard to 'adverse inferences' sometimes helps the consumers. Generally, asking for the medical records through email/whats app or speed post helps the consumer in proving that RMP or the health care service provider is unprofessional and non-supportive.

The medical consumer must know that two legal proceedings on the same matter of deficiency in medical services and medical negligence may run in two different courts, e.g., for monetary compensation, (i.e., civil recourse) a consumer may approach the District Commission, State Commission or National Commission as per Section 34, 47,58, of the Consumer Protection Act, 2019[6]. The cases involving gross medical negligence causing grievous hurt, death, disability, etc. may attract punishment under Bharatiya Nyaya Sanhita, 2023. Additionally, issues such as deliberate withholding or falsification of medical records, (i.e., false evidence), fraudulent practices involving cheating and criminal breach of trust also involve punishment under the relevant sections of BNS. In all such matters, the medical consumers are expected to provide evidences during the court proceedings which include medical literatures proving that the standard care was not provided to the patient and basic protocols were flouted while treatment. Generally, a litigant is supposed to face procedural complexities in any criminal proceedings but, in the cases involving medical negligence, such complexities becomes emotionally and financially exhaustive for patients.

Bharatiya Nyaya Sanhita (BNS), 2023

A medical consumer facing medical mismanagement and malpractice may take reference of BNS 2023 which has replaced the Indian Penal Code (IPC), 1860. This Act helps in understanding criminal laws and defines offences and punishments; it helps a litigant to identify the criminal liability of a health service provider in cases of gross medical negligence.

It has been observed in multiple cases of medical malpractice that the hospital or the RMPs never inform the patient or the attendant about the specific disease and the treatment process involved, and without taking proper consent, the treatment is started, and the outcome becomes fatal for the family and the patient. In such cases, it becomes very important for a medical consumer to understand the meaning of the free consent, and he may refer to Section 28 of BNS, 2023. A careful reading of this section helps us to understand that a consent '*given by a person under fear of injury, or under a misconception of fact or a consent from a person of unsoundness of mind, or intoxication, is unable to understand the nature and consequence*' is never regarded as a consent.

It is pertinent to mention that Section 106 (1) of BNS, 2023 specifically mentions the term 'Medical Procedure' and provides specific punishment for RMPs which is totally different in comparison to the preceding Act (IPC, 1860). Here, it is pertinent to compare the provisions of the earlier act and the new act. Section 304A of IPC deals with causing death by negligence, and states that "*Whoever causes the death of any person by doing any rash or negligent act not amounting to culpable homicide, shall be punished with imprisonment of either description for a term which may extend to two years, or with fine, or with both.*" [7] Now, when we examine Section 106 (1) of BNS, we find specific mention of RMP and while dealing with incidents 'causing death by negligence' it specifies that "*Whoever causes death of any person by doing any rash or negligent act not amounting to culpable homicide, shall be punished with imprisonment of either description for a term which may extend to 5 years, and shall also be liable to fine; and if such act is done by a RMP while performing medical procedure, he shall be punished with imprisonment of either description for a term which may extend to 2 years, and shall also be liable to fine.*" [8] It is to be noted that, for the cases of medical malpractice, death due to wrong diagnosis or prescription, death owing to negligence in surgical process or negligence in post-operative care, along with failure in providing timely emergent treatment will fall under death by negligence. Further to note

that, the term, “registered medical practitioner” means “*a medical practitioner who possesses any medical qualification recognised under the National Medical Commission Act, 2019 (30 of 2019) and whose name has been entered in the National Medical Register or a State Medical Register under that Act*”.[9]

Further, a medical consumer may use Section 105 of BNS in the cases involving ‘*bodily injury as is likely to cause death*’, grievous hurt by negligent act covers cases of negligent treatment resulting in serious and permanent consequences like disability, amputation, paralysis, etc. Section 127 of BNS may be used in the cases of ‘*wrongful confinement*’, i.e., the cases involving refusal of patients discharge due to pending bills.[9]

Pertinent to mention that often we associate the term ‘Medical Malpractice’ with RMPs only but it is quite shocking to find that a lot of *quacks* are practicing medicine in India and are killing innocent patients. According to Indian Medical Association estimates, ‘*about 10 lakh quacks are practicing allopathic medicine*’.[10]Further, as per WHO report cited by Bansal (2025), “more than half of the individuals practicing allopathic medicine in India lack formal medical qualifications, with only 18.8% of allopathic doctors in rural areas being qualified”.[11]The cases involving *quacks* can be addressed by an aggrieved medical consumer through the use of Section 318 (Cheating), Section 336 (Forgery), Section 111 (Organised crime) along with Section 106 (Causing Death by Rash or Negligent Act).

When a medical consumer finds that the health service provider is manipulating the documents to cover up the wrongdoings of one or more medical professional, he may use Section 238 which deals with the matters ‘*Causing disappearance of evidence of offence, or giving false information to screen offender*’. Further Section 125 may be used for the negligent acts of the RMPs which results in ‘*endangering life or personal safety of others*’.

Bharatiya Sakshya Adhinyam (BSA), 2023

Evidence, i.e., Sakshya is very crucial for the litigants in the cases involving medical negligence, in such cases, most of the documentary evidence like, prescription, test reports, medical bills, discharge summaries, consent forms, diagnostic reports, etc. originate through health care service provider. In multiple such cases, the doctors and hospitals either refrain from providing the documents or deliberately delays the same and provide it after alteration and manipulation. This is crucial to note that procedural aspects play a very vital role in criminal cases and the new BSA, 2023 by accepting electronic and digital records has brought a significant change for the aggrieved parties dealing with issues like negligence, mismanagement, non-issuance of medical records, inflated bills, or improper consent, etc. Hence, understanding the meaning, importance, and types of evidence and document for the medical consumers is very important. Section 2 (d) and (e) of BSA, 2023 deals with the term, evidence and document. Evidence means and includes, “*all statements including statements given electronically*”. Electronic evidence includes, “*all documents including electronic or digital records produced for the inspection of the Court and such documents are called documentary evidence*”.[12] Hence, a medical consumer taking legal route must preserve and maintain proper records of all the documentary evidences, along with electronic records like emails, WhatsApp messages, CCTV footage of hospital premises, audio recordings, etc. Hence, specific inclusion of ‘*electronic and digital records*’ is a welcome step in the technology driven society but the vigilance and alertness of the medical consumer is highly required in accumulating, preserving and using them appropriately and judiciously.

Section 56 to 63 of BSA, 2023 deals with admissibility of records and digital evidence. A medical consumer taking legal recourse must refer to these provisions to know about ‘*primary and secondary evidence*’. By using these provisions, a medical consumer can take legal help in the matters of over-billing, denial of treatment, forged consent forms, concealment of patient condition, etc. Section 114, of BSA, 2023 deals with ‘*Proof of good faith in transactions where one party is in relation of active confidence*’.[12] This provision is important in those cases where the hospitals withhold or tamper with records. In these cases, presumptions & adverse inference can be drawn by the courts to hold them guilty on the assumption that the data deleted, tempered or withheld were unfavourable to them. Section 106 of BSA is very important; by using this section the medical consumer can shift the burden of proof on the RMP and the health care service provider who keep and maintain the documents, bills, reports, etc. It says, “*The burden of proof as to any particular fact lies on that person who wishes the Court to believe in its existence, unless it is provided by any law that the proof of that fact shall lie on any particular person*”.[12]

In the cases involving medical malpractices, courts often order for medical expert opinion. The medical consumers must have the idea of the landmark judgement of Hon. Supreme Court in the case of Jacob Mathew *Jacob Mathew v. State of Punjab*, (2005)[1]. According to this judgement, the expert opinion must be sought preferably from a government doctor. In case, the medical consumer gets a favourable expert opinion which highlights the negligence or gross negligence, then the complainant must use Section 39 of BSA and request the court to take appropriate action. This section says that, *"when the Court has to form an opinion upon a point of foreign law or of science or art.... then the opinions upon that point of persons especially skilled in such foreign law, science or art, must be relied."*[12] Medical opinion of an expert may help in establishing whether the treating doctor was possessing required 'qualification and experience' and he followed the established medical protocols and procedure and whether 'standard care' was provided to the patient or not. An expert report helps in establishing the link between the act of error, omission and the resultant injury.

Section 40 of BSA deals with 'facts bearing upon opinions of experts. It basically helps in strengthening or in weakening the expert opinion, this section provides that *"facts, not otherwise relevant, are relevant if they support or are inconsistent with the opinions of experts, when such opinions are relevant"*. [12]

In the cases involving medical mismanagement and malfunctions, medical professionals keep changing their statements. At multiple occasions, the doctors involved in the treatment start blaming each other and try to shift the burden of negligence on each other. In such cases, the complainant may use Section 148 of BSA, 2023 which deals with *'Cross-examination as to previous statements in writing.'* [12]

Bharatiya Nagarik Suraksha Sanhita (BNSS), 2023

BNSS, 2023 acts as a 'procedure manual' of the criminal justice system and it has replaced the Criminal Procedure Code (CrPC), 1973. A legal fight against medical malpractice involves civil/criminal elements and basic knowledge of BNSS along with BNS, BSA, Consumer Protection Act, 2019, the National Medical Commission Act, 2019, etc. can empower a medical victim to understand procedural aspects of civil as well criminal cases and he may well understand the investigation process along with the issues like filing of FIRs, investigation by police, trial and evidence presentation, appeal procedure, etc. It is worth noting that the provisions of BNSS become relevant only when a litigant chooses the criminal route in addition to or instead of a consumer/civil complaint.

A litigant in a medical malpractice case is required to maintain all necessary documents when filing the case as medico-legal evidence. He may also attempt to arrange an independent medical expert opinion to prove gross negligence. It is worthwhile to mention that in India, courts have set a very high level of error or negligence parameter to put a case of medical negligence in the category of "gross negligence" or "rashness", and it requires a high level of commitment and confidence on the part of the litigant to pursue a case of medical negligence.

Section 173 of BNSS deals with *'Information in cognizable cases'* and hence when the litigant is of the strong opinion that the negligence is in the category of 'gross negligence amounting to death or injury' under Section 106 of BNS then he may approach the police station and file an FIR by using provisions of Section 173 and demand a copy of FIR free of cost. Further, this section also permits an "e-FIR" (electronic filing) and "Zero FIR", which empowers a medical victim to lodge a complaint from any location. The medical consumer must know Section 35 which deals with the cases 'when police may arrest without warrant' and this provision may be utilised in the medical malpractice cases committed by quacks. [13]

Section 180 of the Act deals with 'Examination of witnesses by police' while Section 94 of the Act guides about 'Summons to produce document or other thing', i.e., under this section a police officer can procure any relevant *'document, electronic communication, including communication devices, which is likely to contain digital evidence or other thing necessary in the matter'*. [13]

The litigant should also know that according to the provisions of Section 530 of BNSS (Trial and proceedings to be held in electronic mode), all the trials, inquiries and proceedings may be held in electronic mode, which facilitates a medical victim to participate in the legal proceedings without any issues pertaining to distance. Section 397 of BNSS directs *'all hospitals, public or private, whether run by the Central Government, the State Government, local bodies or any other person, to immediately, provide the first-aid or medical treatment, free of cost, to the victims of any offence.....'*, [13] hence this section is based upon Article 21, Right to Life and Personal Liberty and gives a right to demand such

facility from the health service providers and they are bound to provide assistance without any delay or formalities, obviously afterwards police must be informed about the incident.

Drugs & Cosmetics Act, 1940

It is a well-known fact that not only the medical professionals but all those who are in sale or supply of medical equipment and medicines get an opportunity to earn exorbitant profit. In recent times, multiple instances have been reported with respect to sub-standard adulterated medicines. In this regard, a recent news report widely reported in print as well as mass media is worth mentioning. India Today (2025) reported that “*Authorities in Madhya Pradesh and Rajasthan have launched investigations and banned specific cough syrups following multiple child deaths and illnesses.*”[14] The New Indian Express (2025) confirmed that the deaths of kids are happening due to “*acute kidney failure after being prescribed a combination of medicines.....*”[15] Similarly, the Telegraph (2025) reported that, “*multiple children have died of kidney failure following alleged consumption of contaminated cough syrup.....*”[16]

With reference to the above, medical consumers and society at large are required to remain aware with respect to fatal damage to health and well-being due to use of sub-standard, and contaminated drugs. For example, a patient may suffer due to administration of contaminated intravenous fluid or a patient may not get desired result after a joint replacement or stent implant due to the quality issues with the implants. In such cases a medical consumer taking legal recourse may use relevant sections of Drugs & Cosmetics Act, 1940 which is meant to ‘*regulate the import, manufacture, distribution and sale of drugs and cosmetics*’. [17] This is a comprehensive Act that covers the Import, Manufacture, Sale, and Distribution of Drugs and Cosmetics. It is also important to note that the provisions of this comprehensive legislation deal with all categories of drugs used in India, including Allopathic, Ayurvedic, Siddha, Unani, and Homoeopathic systems of medicine.

Section 8 of the Drugs & Cosmetics Act, 1940 deals with ‘Standards of quality’ of Drugs and Cosmetics. Section 9 deals with ‘Misbranded drugs’, whereas Section 9 (A) to 9(D) deals with Adulterated drugs, Spurious drugs, Misbranded Cosmetics, and Spurious cosmetics. Section 10 of the Act, deals with ‘*Prohibition of import of certain drugs or cosmetics.*’[17] Section 16 of the Act defines ‘Standards of quality’ for a drug and cosmetic, whereas Section 17 A to E deals with Misbranded, Adulterated, and Spurious, drugs& cosmetics. Section 18 deals with ‘*Prohibition of manufacture and sale of certain drugs and cosmetics.*’ [17]

It is important to note that, Section 26 of this Act empowers the ‘Purchaser of drug or cosmetic’ to submit a drug or cosmetic for test or analysis and obtain a report signed by the Government Analyst on payment of a prescribed fee. Section 27 of the Act prescribes, ‘*Penalty for manufacture, sale, etc., of drugs in contravention of this Act.*’ Additionally, Section 34 of the act deals with ‘offences committed by companies’ and Section 34-A deals with Offences by Government Departments. [17]

Thus, the provisions of Drugs and Cosmetics Act, 1940, are not directly related to the cases of medical negligence but in those cases where a medical consumer who has suffered due to *use of substandard or misbranded drugs or medical devices* administered by a health care provider can use the relevant provisions against the RMP or the concerned manufacturer or hospital management as the case may be.

Conclusion & Suggestions

This article aims at highlighting the importance of legal awareness and the necessity of understanding the complexities involved in medical negligence cases. It must be accepted that contesting a medical negligence case requires a high level of attention, involvement and knowledge on the part of the litigant. Such an awareness saves the litigant from unwanted legal hassles and difficulties. Along with legal awareness, the litigant must be familiar with his own specific case, and they should examine the medical literature and seek help from medical professionals before approaching any legal body. Understanding the meaning of ‘gross medical negligence’, the ‘medical protocols’, along with deviation from the standard protocol, must be properly examined before taking a legal action. A medical consumer who is confident about the occurrence of medical malpractice must seek legal help because a medical victim is required to create moral pressure on healthcare providers and to minimise cases of medical negligence. Medical professionals will remain aware and cautious while treating the patient, and they will feel pressure due to societal awareness. Often, medical consumers refrain from seeking legal recourse against healthcare providers, which creates a false sense of security among medical professionals and hospitals that no one will come forward to expose their wrongdoings. As a result, many continue to treat

patients with a casual and negligent approach. Therefore, it becomes essential for medical consumers who have suffered due to gross medical negligence and mismanagement to come forward and pursue legal action with confidence; not only to protect their own rights and interests, but also to ensure accountability for the greater good of society.

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