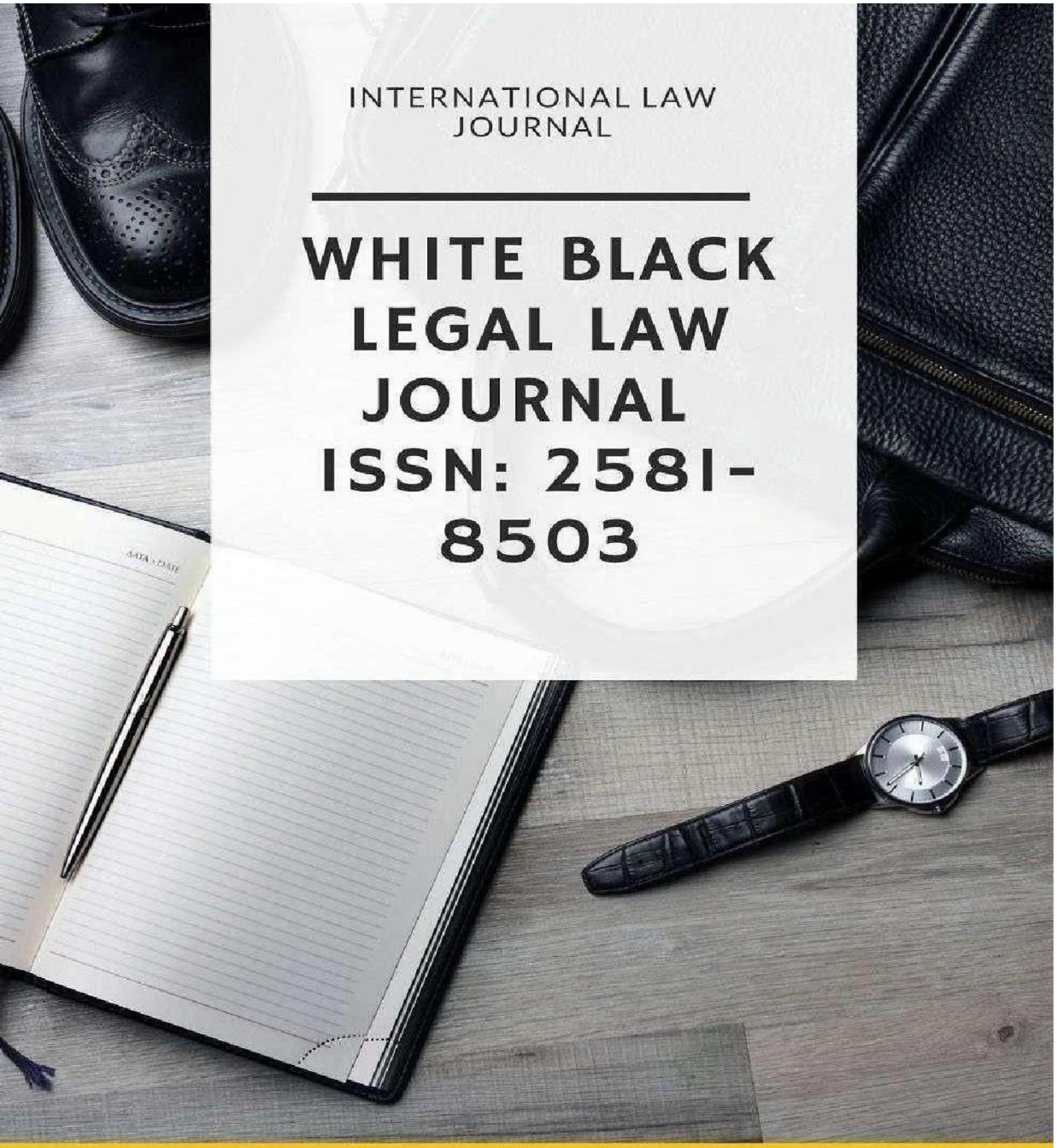

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THE ROLE OF THE JUDICIARY IN CLINICAL TRIAL REGULATION IN INDIA: TRACING THE GAP BETWEEN PROCEDURAL REFORM AND COMPENSATION OUTCOMES

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Abstract

The India's clinical trial regulatory regime is defined by the Drugs and Cosmetics Act 1940, New Drugs and Clinical Trials Rules 2019 along with subsequent recommendations by the ICMR, but it has been rather exhaustive without ever proving to be successful in preventing any of the harm that it was meant to avoid, requiring direct action in the court of law. In this paper, the question of filling that implementation gap with the judiciary is examined, and the Supreme Court's approval of requesting audiovisual recordings of informed consent in Swasthya Adhikar Manch (SAM) v. Union of India, which mandates three-tier trials for approval of this screening, is discussed. The report, however, found little to no effect from this intervention on the compensation outcomes for wounded participants or for bereaved families in theory. This is because the changes made by the court do not seem to have left any visible trace in any of these areas. The paper reveals shortcomings of the compensation formula, such as its methodology of money-wages being used in a labor-law field of activity that affects economically disadvantaged individuals and the application of labor-law actuarial logic in a land-law field of activity that was described constitutionally. It is a doctrinal analytical approach and secondary empirical data, most of all RTS's own campaign funnel of taxes over 20+ years of a trial and adverse events and compensation. A public interest case filed by the same petitioners in 2025–26, to address anomalies in clinical trials across 58 clinical trials at a hospital in Ahmedabad, ten years after the initial litigation, finds the same basic implementation issue. The study recommends a public compensation-outcomes database, includes new reporting parameters for investigator-initiated research, and ongoing judicial or

independent oversight of implementation, which the study points out has been a needed but insufficient "remedy. The public interest litigation norm, drug legislation, informed consent, clinical trials, the court, India, compensation, and Swasthya Adhikar Manch are some of the topics covered.

Keywords – Clinical Trials, Drug, Compensation, NDCT, Consent, Judiciary.

1. Introduction

There are many paradoxes in the regulatory system in India for clinical trials. The Drugs and Cosmetics Act 1940 and the New Drugs and Clinical Trials (NDCT) Rules 2019 along with the ethical guidelines laid down by the ICMR provide a comprehensive legal framework to protect the research participants involving human beings. This system never existed to allow unregistered or inadequately monitored trials, inadequate informed consent, or inadequate compensation for damage and death, all of which have happened frequently without court intervention. This paper examines how the judiciary has tried to fill that gap in the implementation, taking the Swasthya Adhikar Manch v Union of India proceeding of the Supreme Court as an example. In its inquiry, it poses a question rarely addressed in the literature: has the presence of the judiciary served to result in better outcomes for the parties involved in the trial or simply acted to facilitate procedural reform without any apparent results?

The involvement of the Indian judiciary in the regulation of clinical trials has been extensive from a doctrinal perspective but has not been monitored from an empirical point of view, the article argues. In 2012-2013, in the Swasthya Adhikar Manch case, the Supreme Court imposed new restrictions on trials, such as a legally-formulated risk-benefit and unmet-need test, an audio-visualrecord of informed consent, and a three-stage screening procedure for trial clearance. These were things within the foundation or base of the building that needed to be rectified. The same petitioner organization has a history of an incident in 2025-26 that seemingly would not have been addressed had the fundamental concern not existed more than 10 years later, and no evidence in the public domain, auditable, and up-to-date of linkages were found to help quantify the improvements in compensation outcomes for hurt participants or bereaved families. This research is a development of that vacuum and nestled in a wider discourse on the scope and role of PIL in such technically advanced and data oriented sectors.

2. Literature Review

The subject covered in this research is not directly addressed in any literature on clinical trial regulation in India which can be classified into three broad categories. The key and long-standing wing is doctrinal – regulatory, which comprises a detailed analysis of the Drugs and Cosmetics Act, the new Drugs and Cosmetics Rules 2019 and ICMR guidelines. Such a review is typically conducted in a comparative regulatory/compliance regulatory perspective and tries to harmonize Indian regulatory standards with any foreign regulatory standard such as ICH-GCP. The second set of works are in the field of public health and bioethics. It describes trends of vulnerable participating groups including the over representation of poor, rural, and uneducated participants in these studies and the informed consent and exploitation issues. The litigated case of the Swasthya advhkar manch is mentioned as an historic case, but is said to have provided "historical background" to the case, and significantly fewer people have dissected it as a ongoing matter on a doctrinal level. Investigative or journalistic reporting, like the RTI's reporting of trial deaths, adverse events and compensation by the Wire Science, represents the third strand. This dataset is the only systematic one in the public domain, but it doesn't deal with the doctrinal content of the litigation or how it relates to the data.

There are no visible signs of sustained scholarly and legal debate regarding the role of the judiciary as an institution and in all three streams in particular regarding whether the court-ordered processes implemented in 2013 have made any meaningful difference to the speed, consistency or effectiveness of payments. Most of the current literature is based on the procedures of the orders issued in 2013, including the three-tier screening process and audio-visual consent, but skips any mention of the trajectory of litigation through the Supreme Court until 2017 when the case remained before the Court. Most current commentary is limited to the procedures of the 2013 orders – including the three tier screening process and audio-visual consent – without making any connection to the precedent that had been set in the files of the investigative reporting, which found its way onto the Supreme Court docket in 2017 and was still pending. Besides, the case of Ahmedabad did not involve academics since it occurred after the bulk of research in this area was done, and the accusations are highly similar to those made in the 2025–26 case. In response to that void, the article reads the court itself - not simply as a background to legislative history - and it challenges the hypothesis that there are relationships - or subset – between judicial mandate and the empirical outcome.

3. Methodology

The research methods are doctrinal analytical with secondary empirical sources that are obtained from investigative reports and disclosures of regulators. The doctrinal part analyses the chronological content and subject-matter of all decisions of the Supreme Court in Swasthya Adhikar Manch v. Union of India (2012-2017) in the context of the compensation rules provided in the NDCT Rules, 2019 and the earlier series of rules issued by CDSCO in 2013. A case-study analysis of a clinical trial error that caused a public interest litigation in Ahmedabad in 2025-26 is calibrated to further explore whether the trends identified in the previous year (2012-13) persist. In the absence of an open source dataset reporting recruitment outcomes alongside the judically-required reforms, this paper employs a dataset of compensation outcomes measured by RTI, which has been published by The Wire Science between 2011 and 2020. It must be acknowledged, however, that the information contained in this resource (and information in general) is not comprehensive, and cannot be relied upon as an exhaustive list. This is because the organisations under study do not have any primary data produced, so this research identifies a gap which will have to be addressed with a combination of doctrinal tracing and a secondary empirical triangulation.

4. The Judiciary's Doctrinal Intervention

In 2012, Writ Petition filed by the Swasthya Adhikar Manch arose and spread a wave of claims of suppressive clinical trials for various reasons, including the cases of both public and private organizations in India. petitioners raised issues in respect of under- reporting of deaths, serious adverse effects and inadequate compensation. The Supreme Court gave several interim orders from October 2012 to December 2013, mandating that the CDSCO and the Ministry of Health and Family Welfare make certain data on approvals for trials available and refine the monitoring of institutions. By October 2013, the clinical trial approval process would have to be completed through three levels of screening and informed consent would have to be signed with mandatory audio-visual technology. This was a big change from the paper-based consent practices that had previously been used.

These two frames of evaluation, along with the value of the IP relative to available treatment, the risk benefits for participants, and the country's real need for the IP led the Court to arrange its rulings for trials. Using this methodology, the courts found that the technical and apex committees had to review 157 trial approvals that came after January 2013 which had not been

done thoroughly. It was far from just another administrative change—it was a judicial reshuffle of the approval process resulting from the failure to make the CDSCO and the Drug Controller General effective gatekeepers.

Two aspects of this intervention are crucial to the thesis that is advanced later on in the article. A significant feature of the changes is that they are well framed in terms of the Constitution. They want a judicial review to be afforded in relation to what is ostensibly a technical area of regulation on the basis of respect of life and personal liberty guaranteed under Article 21. Secondly, the 2013 directives were not the end of the struggle by Bhopal Gas victims and others to be added to clinical trials—they raised more arguments as late as October 2017. The fact that the reform is still securing new litigants five years after its most publicized substantive crossing of the line suggests the continuation of the reform process and does not mean that it is completed. The continuous obligation of the Court to secure new litigants five years after its most popular substantive reform order raises the question as to its persistence or resolution.

5. The Compensation Blind Spot

The investigation news outlet, The Wire Science does not get its information from the Indian judiciary, transparency practice of the CDSCO, or an Parliamentary inquiry but rather via the exercise of RTI applications, it has been able to acquire the most comprehensive "empirical record" of clinical trial deaths, adverse events and compensation between 2011 and 2020. There were 4,506 deaths among the people who took part in the trials during this period. Of these, an expert causality-review process only attributed an experiment to 311 deaths, averaging around ₹8,43,533 per family of the deceased. 22,487 (1,720 of which were experiment-related) were recorded in the form of severe adverse events (SAEs). This data is accompanied by 2 structural qualifiers. The Drug Controller General does not have to accept such reports of SAEs from academic or investigator-initiated studies. This means there exists an unnamed population who do not fall into this category for being reported and compensated. Secondly, no independent methodology audit has ever been conducted on the causality-determination ratio, the actual clinical reality or a systematic bias of committees appointed by the regulator who authorized trials to draw conservative conclusions. This ratio represents less than 7% of fatalities and less than 8% of SAEs that are trial-related.

The compensation formula raises an important theological challenge, and it is important to

emphasise it. Death compensation ranges between ₹8 lakh and ₹73.6 lakh and this is calculated by multiplying a basic component of ₹8 lakh with an age factor based on the Workmen's Compensation Act and a risk factor ranging from 0.5 to 4, depending on pre-existing condition. Whereas in the case of Swasthya Adhikar Manch, the Supreme Court intervened in the name of Article 21 in the Constitution of India. The quantum of the compensation in operationalizing a violation of the right to life, however, is not based on the constitutional value of the life lost in medical research, but rather on an actuarial logic adopted from labour law. This regime is founded on an employer's responsibility for workplace injury. The compensation for a reversible SAE which is cured is based on the minimum wages of minimum skilled worker in Delhi multiplied by the number of days spent in hospitalisation. This leads to a systematic under compensation of those that participate in the programme in contrasting regions or different social and economic groups, depending on the wage rates. As per the wider literature, lower wages for rural and economically marginal communities, over-represented in the selection for a trial, is particularly stark.

While there is aggregate compensation information available, no doctrinal, regulatory, or empirical research has shown a connection or causal link between the 2013 judicial reforms and any resulting gain in sufficiency, uniformity, or timeliness in the amount of compensation actually disbursed to judges. The data currently available cannot be segmented by research period (before or after 2013) or by whether or not the research required the screening that the Court set. Therefore, it's difficult at this early stage to determine from current data if the "court system process" is positively or negatively affecting compensation outcomes or whether it is having no impact at all. The most noteworthy unresolved issue in the movie as far as court interaction with clinical trial regulation is concerned, is that there is no foundings, which is an evidential gap, uncovered in the literature.

6. Persistence of the Problem: The 2025–26 Ahmedabad Episode

Comparing them to another incident, we can see how long the changes from 2013 last up. In October 2025, the same petitioner NGO (Swasthya Adhikar Manch), made fresh allegations that an investigator at an Ahmedabad municipal hospital misconducted itself. An initial probe resulted in the dismissals of several contractual physicians after illegalities were uncovered in 58 research projects underway. One investigator said that the changes were mainly in the clinical-safety screening and consent forms but did not impact the administration and financial

aspects of conducting trials, which is where the controversy arose from. The fact that identical concerns that led to harms to participants have been raised in the same organization for a decade or more after the initial litigation that instigated it makes it clear that even the most doctrinally compelling judicial actions were ultimately unsuccessful in fundamentally altering the situation that injured the people. The question of whether or not wounded participants of the hospital in Ahmedabad received compensation and when was still unanswered and not tracked, as a real test for the same gap pointed out above in Section.

7. Findings and Discussion

This investigation leads to 3 conclusions. First, the Indian judiciary has been quite engaged addressing the issues of regulation of clinical trials, but in the process without any real intent to produce results. Courts with PIL jurisdiction tend to be adept at issuing “one-off” structural remedies such as screening tiers and consent recording provisions, but aren't so good at mandating the continuous in addition to continuous data infrastructure needed to ensure that those structural measures are effective. One of the core limits of writ-based reform, not only in this case, is the courts' reluctance to grant perpetual supervision when interim relief finally moves towards ultimate oversight in technically complex and data heavy regulatory fields. Second, the compensation system supposedly that is supposed to address the constitutional issues of the judiciary is flawed. It is based on actuarial reasoning from labour law, which they said forms one of the fundamental rights, and incorporates wage-linked distortions that work to the disadvantage of the marginalised (groups which tend to be overrepresented in trials). Lastly, the instance in 2025-26 proves that the gap in implementation that exists since 2012 is present in another form today – that of financial and administrative irregularities – but not consent or screening failures. This implies judicial reform was only about specific malpractices that had been taking place in 2012 and not the systemic issues that created new malpractices.

The results corroborate the main argument of the paper, which states that judicial intervention has been an important step in fixing the regulatory failure in this area, but it hasn't gone far enough. Arrangements it has put in place are substantial but there is as yet no empirical accountability to support the effectiveness of its structural safeguards.

8. Recommendations

This study proposes three steps to try to close the gap. The first step would be the NDCT Rules 2019 making it mandatory for the CDSCO to create an annual, consolidated compensation-outcomes register. This register must separate trials that fall within the high intensity test from trials that do not fall under the high intensity test and clearly identify how long it takes to disburse the money in terms of the statutory deadlines. Secondly, there are currently unknown to the public numbers of participants on which reporting of remuneration does not yet occur, and so this should be expanded to cover academic and investigator-initiated studies. A future PIL bench dealing with a systemic failure in the regulatory system should also look at continuing jurisdiction in part or at setting up an independent monitoring institution over the system to language the aforementioned structural deficiency pointed out in Section 7. This body would have a specific mandate to periodically present to the public the work being done in its implementation. This would eliminate Court's involvement in the management of the data infrastructure.

9. Conclusion

This article has argued that there is a shortage of a reliable empirical history of judicial involvement and outcomes in India's clinical trials framework despite the importance of this involvement on doctrinal issues. Although the Supreme Court's engagement with Swasthya Adhikar Manch did lead to some real structural change, there is no evidence of the change for bettering the populations it was supposed to benefit, namely the adequate compensation, consistency and timeliness with which they are provided for. Nor have any subsequent studies or regulations shown signs of such changes. This gap is not history as the same or similar damage occurred in 2025 and, in 2026. Because there is no empirical evidence that judicial protection is effective in this area, claims can only be made on the basis of theoretical achievements and not actual results for the people or groups that the laws on judicial protection were designed to benefit.

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