IN THE SUPREME COURT OF INDIA
CIVIL WRIT JURISDICTION

WRIT PETITION (CIVIL) NO. _____ OF 2016

IN THE MATTER OF

Dinesh S. Thakur
103 A, Thomas Prabhu Reliance Complex,
First floor, 3-6-278, Opp. Dr. P.Shiva Reddy Eye Hospital
Himayatnagar, Hyderabad Pin 500029
Telangana State .....Petitioner

Versus

Union of India;
Through its Secretary,
Ministry of Health & Family Welfare,
Nirman Bhavan, Maulana Azad Road,
New Delhi, 110011 .....Respondent

A PETITION UNDER ARTICLE 32 OF THE CONSTITUTION OF INDIA FILED IN PUBLIC INTEREST

To,
The Hon'ble Chief Justice of India and
His Companion Judges of the
Supreme Court of India

MOST RESPECTFULLY SHOWETH:

1. This Public Interest Litigation (PIL) is filed by the petitioner, in public interest, challenging the constitutionality of Rules 69, 69A, 70, 70A, 73, 73A, 75 & 75A of the Drugs & Cosmetics Rules, 1945 through which the Central Government sub-delegates to 36 different State Governments/U.T. Administrations, the power to appoint licensing authorities to grant or renew licences, for

manufacture of certain class of drugs. It is the humble submission of the Petitioner that such sub-delegation is unconstitutional because Parliament had specifically amended the Drugs & Cosmetics Act, 1945 in the year 1955 to centralise drug licensing activities as it was felt that the presence of multiple licensing authorities under different state governments was leading to inefficient regulation of the pharmaceutical industry and adversely affecting public health. The Central Government however ignored the legislative intent behind the legislative amendments enacted in 1955, when it exercised its power under Section 33 of the Drugs & Cosmetics Act, 1940 to amend the Drugs & Cosmetics Rules, 1945 to unconstitutionally sub-delegate its own licensing powers to 36 different licensing authorities, each of which operates under different state/UT authorities. While delegation of powers from the legislature to the executive is legal, it is blatantly unconstitutional for the Central Government to sub-delegate powers to State Governments when Parliament has not expressly authorised the Central Government to sub-delegate such powers.

I. ABOUT THE PETITIONER

2. It is humbly submitted to this Hon'ble Court that the Petitioner is an Overseas Citizen of India (OCI), currently residing in India. The petitioner is a public health activist, who after almost 20 years of experience working in a

number of different positions in both the Indian and American pharmaceutical industry, turned a whistle-blower, at great personal risk, against his former employer Ranbaxy Laboratories Ltd. ("Ranbaxy") who were involved in widespread data falsification in order to secure marketing approvals for its products. The petitioner had secured access to this information regarding falsification of the data while working as the Director & Head of the Research Information and Portfolio Management at Ranbaxy from 2003 to 2005. Although the petitioner had made repeated attempts to convince the senior management to take corrective action, his attempts went un-heeded. Instead his position was compromised by the company thereby making it difficult to continue his employment. He resigned from his role and worked with the US Food & Drug Administration as a confidential informant between 2005 and 2007. In April of 2007, he filed a lawsuit against Ranbaxy in the United States of America ("US") under the Federal False Claims Act and similar state laws on the grounds that Ranbaxy was supplying substandard medicine to government agencies in the US. (*United States ex rel. Dinesh S. Thakur v. Ranbaxy USA Inc., et. al.,* Civil Action No. 1:07-00962-JFM (D. Md.) The United States government simultaneously initiated civil & criminal proceedings against Ranbaxy on the basis of information submitted by the petitioner. (*United States of*

America v. *Ranbaxy Laboratories Ltd. et.al.* Civil Action No. 12-250 (D. Md.)

3. In May 2013, after a long legal battle, Ranbaxy pleaded guilty to seven counts of felony charges and agreed to pay $500 million in penalties & fines to the United States government in order to resolve the various criminal and civil claims in the US District Court of Maryland. Under the provisions of the False Claims Act, the petitioner was awarded a sum $48 million dollars for risking his career and his life in order to expose the wrongdoings at Ranbaxy, for saving public funds and most importantly for saving the lives of millions of patients who consume substandard medication manufactured by Ranbaxy.

4. In recognition of the petitioner's role in uncovering this criminal behaviour, he has beenrecognized through awards and honours including the Joe. A. Callaway Award for Civic Courage, the Association of Certified Fraud Examiners (ACFE) Cliff Robertson Sentinel Award, Taxpayer AgainstFraud (TAF) Whistle blower of the Year. From the settlement amount received, the petitioner has contributed generously to various charities in India and abroad, including the supporting Gyanshala, a charitable school for children in UP and Bihar, and Cankids, a charitable institution for care of children with cancer. The petitioner

also contributes to educational causes by funding fellowships in his *alma matter*, the University of New Hampshire for research in bioengineering and in healthcare analytics. He also offers professional services through his company Medassure Global Compliance Corporation for improving the quality of medicine to the pharmaceutical industry.

5. Over the last two years, the petitioner has dedicated a substantial amount of his time and resources towards improving the quality of regulation of the pharmaceutical industry in India by conducting research, giving talks, writing academically and for newspapers to increase awareness for the issue of pharmaceutical regulation in India. During this period of time, the petitioner through his research has discovered substantial shortcomings in the manner in which the pharmaceutical industry is regulated in India, including in some cases the non-application and misinterpretation of the Drugs & Cosmetics Act, 1940 by statutory authorities who are responsible for implementation of the legislation.
6. One of the most important issues discovered by the petitioneris that the multiplicity of licensing authorities in India is one of the main causes behind poor standards of regulations of the pharmaceutical industry. Keeping in mind the need for a more efficient drug licensing scheme in India, the Petitioner felt compelled to challenge the pertinent

provisions of the Drugs & Cosmetics Rule, 1945 which have illegally sub-delegated power to 36 different State Governments/U.T. Administrations.

II. LEGISLATIVE HISTORY BEHIND THE DISTRIBUTION OF POWERS BETWEEN THE CENTRE & STATES UNDER THE DRUGS & COSMETICS Act, 1940

7. The legislative history of the Drugs & Cosmetics Act, 1940 can be split into two broad phases: pre-independence and post-independence.

The pre-independence regulatory regime of the pharmaceutical industry:

8. The first steps to enact a new drug regulatory law began was taken by the Government of India, when in consultation with the provincial governments, it issued a resolution on 11th August, 1930 appointing a committee, called the Drugs Enquiry Committee, with a mandate to:

(i) Enquire into the extent to which sub-standard and adulterated drugs were being imported into British-India and make recommendation on the requirement to control such imports;

(ii) Whether the recommendations for imports could apply to even indigenously manufactured drugs; &

(iii) To enquire into the necessity of legislation to restrict the profession of pharmacy.

9. After holding extensive consultations with the medical community, the pharmaceutical industry and other stakeholders and conducting a detailed review of drug regulation in other countries, the Committee submitted a 174 page report to the Government of India on 29th March, 1931.

10. Regarding the need for legislation to regulate the drug industry, the Committee recommended that “there should be legislation to control drugs” and that “legislation should be central with a view to secure effectiveness and uniformity in control throughout India.” However, one potential roadblock at the time was whether the Indian Legislature at the centre, would have the powers to legislate on a uniform legislation for the entire country. According to the Committee, the Devolution Rules under Section 45-A of the Government of India Act distributed legislative powers between the Indian Legislature and the various provincial assemblies. (para 491) The subjects of medical administration, public health, adulteration of articles, control of poisons, development of industries etc. were under provincial purview. The Committee however argued that a Central legislation was still possible because not only was some of the subject-matter on the provincial list, subject to the Indian legislature but also because the Government of India Act allowed the

Indian legislature to legislate on provincial subjects with the prior sanction of the Governor General.

11. On the basis of recommendations by the Drugs Enquiry Committee, a Bill was introduced in 1937 in the Central Legislative Assembly to regulate the import of drugs into British India. The Bill was referred to a Select Committee which recommended a more comprehensive bill to regulate even the domestic manufacture and distribution of drugs. In order to widen the ambit of the legislation, the Government of India wrote to the provincial governments to request their respective provincial assemblies “to pass resolutions under Section 103 of the Government of India Act, 1935 empowering the Central Legislature to pass an Act for regulating such matters relating to the control of drugs as fall within the Provincial Legislative List” in the Seventh Schedule to the Government of India Act, 1935. Once the various provincial assemblies passed such resolutions, the Government of India introduced a Bill in the Indian Legislature which was eventually enacted as the Drugs Act, 1940 (cosmetics were included, within the ambit of the legislation and its title, only in the year 1962).

12. Although enacted as a Central Legislation, the Drugs Act, 1940 split regulatory powers between the Centre & Provinces. The Act delegated substantial powers to both the

Central and the Provincial Governments to draft rules for the setting of standards for their respective areas of regulation i.e. import and domestic manufacture/sale, respectively. Section 33 as it existed in 1940 specifically delegated to the Provincial Governments the power to issue licences for the manufacture of drugs and also the power to nominate the authority empowered to issue such licences. The language of Section 33 as it existed in 1940 is reproduced as follows:

*Section 33 (1) The **Provincial Government** may, after consultation with the Board and after previous publication by notification in the official Gazette, make rules for the purpose of giving effect to the provisions of this Chapter.*

(2) Without prejudice to the generality of the foregoing power, such rules may-

(e) prescribe the forms of licences for the manufacture for sale, for the sale and for the distribution of drugs or any specified drug or class of drugs, the form of application for such licences, the conditions subject to which such licences may be issued, the authority empowered to issue the same and the fees payable therefor;

True and correct copy of the original Drugs Act, 1940 is annexed herewith as **ANNEXURE P-1**.

13. On the basis of this provision, the various provinces in British India, notified their own set of rules such as the Bombay Drug Rules, 1946; West Bengal Drug Rules, 1946 & the Madras Drug Rules, 1945 etc.

14. **The post-independence reform aimed at consolidating drug regulation in India by enacting the Drugs (Amendment) Act, 1955:** The first post-independence amendments to the Drugs Act, 1940 was by Parliament when it enacted the Drugs (Amendment) Act, 1955. This legislation made an important change to the scheme of the Drugs & Cosmetics Act, 1940 by transferring to the Central Government, the powers under the original Section 33 of the Drugs Act, 1940. As explained earlier in this petition, the originally enacted Section 33 in 1940, delegated substantial powers to the erstwhile ***provincial governments*** (now called the state governments) to formulate rules for all the provisions under Chapter IV of the legislation which dealt with 'manufacture, sale and distribution' of drugs. The amendments in 1955 altered the language of the erstwhile Section 33 to transfer these powers to the ***Central Government***. In specific the amended Section 33read as follows:

*Section 33 (1) The **Central Government** may, after consultation with the Board and after previous publication by notification in the official Gazette, make rules for the purpose of giving effect to the provisions of this Chapter:*

Provided that consultation with the Board may be dispensed with if the Central Government is of opinion that circumstances have arisen which render it necessary to

make rules without such consultation, but in such a case the Board shall be consulted within six months of the making of the rules and the Central Government shall take into consideration any suggestions which the Board may make in relation to the amendment of the said rules"

It should be noted that there was no amendment to the existing Sub-section 33(2)(e) but since the title of the section was itself altered, **all the existing powers of the State Government were now transferred to the Central Government**. The current language of Sub-Section 33(2)(e), after subsequent amendments, and as it currently exists in the statute books, is reproduced below:

(e) prescribe the forms of licences for the manufacture for sale [1][or distribution], for the sale and for the distribution of drugs or any specified drug or class of drugs [2][or of cosmetic or any specified cosmetic or class of cosmetics], the form of application for such licences, the conditions subject to which such licences may be issued, the authority empowered to issue the same, [1][the qualification of such authority] and the fees payable therefor [1][and provided for the cancellation or suspension of such licences in any case where any provision of this Chapter or the rules made thereunder is contravened or any of the conditions subject to which they are issued is not complied with;]

15. With this amendment, the Central Government was given complete responsibility for regulating the domestic manufacture of drugs and import of drugs. Until these amendments, the Central Government had the responsibility of regulating only imports.

16. The legislative intent behind these amendments is significant. The "Statement of Objects & Reasons" (a legitimate aid to statutory interpretation), to the Drugs Bill, 1954 explains that one of the motivations for the amendments in the following words:

It has further been found necessary that with a view to maintaining uniformity throughout the States the power to make rules under Chapter IV with respect to the manufacture, sale and distribution of drugs, which is at present vested in the State Governments should be entrusted to the Central Government.

17. Similarly the Minister's statement in Parliament during Parliamentary debates can be used as an aid to interpreting a statute. During the discussion in the Rajya Sabha the Minister of Health while introducing the Bill on August 31, 1954 told the Council that:

And there was need also, in the present circumstances, for the assumption by the Central Government of rule-making

powers, which up till now had been in the hands of the States, in order to have a uniform policy.

18. During the discussion in the Lok Sabha on February 28, 1955 the Minister made a similar statement saying:

One of the main amendments is the assumption by the Central Government of rule-making powers under chapter IV. I may say that the States are absolutely in agreement with us on this. Many of the important drugs in the country are imported and because they enter into inter-state commerce, it is essential that the rules governing their standards should be uniform throughout India.

19. It is also important to note the recommendations made in the Report of The Pharmaceutical Enquiry Committee in 1954 which is the same year in which the Drugs (Amendment) Bill, 1954 was introduced in Parliament. In pertinent part, the Committee had argued for a central regulator on the following grounds:

3.7 *In order to overcome these defects in the operation of the drug control existing at present and to bring about a uniformity in the standards of products manufactured, we strongly recommend that the administration of Drug Control should be centralised by bringing control on manufacture, sale and distribution, which is, at present exercised by the State Drug Controller, under the control of the Drugs*

Controller (India). This will help to bring about a uniform enforcement of the Drugs Act and a better co-ordination in the administration of the Drugs Act and the Industries (Development & Regulation) Act. The manufacturers, importers, medical men, retail traders and others interested in this industry have also unanimously represented through their respective organisations asking for a centralisation of the entire drug control administration in the country. As "Drugs" is a concurrent subject in the Constitution, we feel, that there will be no difficulty in the Central Government taking over control on manufacture, sale and distribution, which is, at present, exercised by the State Drugs Controllers and bringing it under the control of the Drugs Controller (India).

6.4.2. In very many States, the Drugs Act is so poorly administered that we found that factories, which had been licensed were located in unsanitary places and their premises maintained in no better conditions. They also had no proper equipment for manufacture or testing and neither the manufacturers nor the State were exercising any control on the quality of the products made by them. The products of these factories were a menace not only to the particular State, in which they were located, but also to the neighbouring States, to whose market they found their way. The people of the neighbouring States were in no way benefitted in spite of the fact that the Act was being

administered there in a better manner. When these points were brought to the notice of the State Drugs Controllers, they appeared to be helpless in the matter, either because they were afraid that by closing down such factories, it might lead to employment, labour unrest etc., or they had their own misgivings of the powers delegated to them under the Drugs Act to take such steps. It is, therefore necessary to centralise the administration of the Drugs Act to bring about a uniform implementation of the Drugs Act throughout the country for proper co-ordination with the working of the Industries (Development & Regulation) Act to be possible.

20. It is also important to refer to the 'Statement of Objects and Reasons' of the Drugs (Amendment) Bill, 1960 which stated in pertinent part, the following:

The Pharmaceutical Enquiry Committee appointed by the Government of India to make a comprehensive survey of the pharmaceutical industry, trade and profession in the country unanimously recommended that the Drugs Standard Control which was exercised by State Governments should be centralised for a better enforcement of the Drugs Act, 1940. On the basis of this recommendation of the Committee it is proposed to amend the Drugs Act, 1940 so as to empower the Central Government to control the manufacture of drugs, to appoint Inspectors for inspecting manufacturing premises and taking samples of drugs, to

appoint Government Analysts to whom samples drawn by such Inspectors could be sent for analysis and to issue directions to State Governments for carrying into execution any of the provisions of the Act.

21. The above extracts give the historical context of the Drugs (Amendment) Act, 1955. Read together with the Minister's statements in Parliament and the "Statement of Objects & Reasons" accompanying the 1954, Bill & the subsequent Drugs (Amendment) Bill, 1960 it is amply clear that the legislative intent at the time appears to have been aimed at centralizing certain aspects of drug regulation such as rule-making and licensing of manufacturing units because of difficulties being faced with multiple licensing authorities in different states. Unfortunately, the amendments in 1960, to the Drugs & Cosmetics Rules, 1945 did not reflect the legislative intent behind the Drugs & Cosmetics Act, 1955.

22. The amendments to the Drugs & Cosmetic Act, 1940 in 1955 were followed by amendments to the Drugs & Cosmetics Rules, 1945 in 1960. Since each State, prior to 1960, had its own rules governing the issue of manufacturing licences; the Drugs & Cosmetics Rules, 1945 as originally notified by the Central Government, in 1945, regulated the issue of licences for manufacturing only in the Chief Commissioner's Provinces that were created under

Part IV of the Government of India Act, 1935. The relevant rule in this regard was Rule 69. The amendments in 1960 to the existing Rules, basically substituted the phrase 'Chief Commissioner' in Rule 69 with 'State Government'.

23. Both the old Rule 69 (pre-1960) and the existing Rule 69 are reproduced below:

(Pre-1960 amendments to Drugs & Cosmetics, Rules, 1945)

69. Applications for licence to manufacture drugs other than special products.- Applications for the grant or renewal of licences to manufacture for sale drugs other than those specified in Schedules C and C(1) shall be made to the licensing authority appointed by the ***Chief Commissioner*** *for the purposes of this Part (hereafter in this Part referred to as the licensing authority) in Form 24 and shall be accompanied by a fee of rupees twenty.*

True and correct copy of the relevant extracts of the Drugs Rules, 1945 is annexed herewith as **ANNEXURE P-2**.

(Post-1960 amendments to Drugs & Cosmetics, Rules, 1945)

69. Application for licence to manufacture drugs other than those specified in Schedules C and C(1) to the Drugs and Cosmetics Rules.___

[2][(1) Application for grant or renewal of [4][licence to manufacture for sale or for distribution]of drugs, other than those specified in Schedule C and C (1) shall be made to the licensing authority appointed by the ***State Government*** *for the purpose of this part (hereinafter in this part referred to as the licensing authority) and shall be made--*

(a) in the case of repacking of drugs excluding those specified in Schedule X for sale or

distribution in Form24-B;

(b) in the case of manufacture of drugs included in Schedule X in Form24-F;

(c) in any other case, in Form 24.]

True and correct copy of the amendments to the Drugs Rules in 1960 are annexed herewith as **ANNEXURE P-3.**

24. From the above amendment, it appears rather obvious that despite the amendment to Section 33 being effected by Parliament with the aim of transferring all the licensing powers of the State Governments to the Central Government, the subordinate legislation i.e. the Drug Rules, 1945 was amended by the Central Government to give licensing of manufacturing activities back to the State Governments. Thus the amendment in 1960 to the Drug Rules, 1945 clearly went against the legislative intent behind the Drugs (Amendment) Act, 1955 to centralise all licensing of manufacturing activities with the Central Government and is therefore *ultra vires* the Drugs (Amendment) Act, 1955.

III. THE CONSEQUENCES OF HAVING 36 DIFFERENT LICENSING AUTHORITIES ACROSS INDIA

25. It is humbly submitted to this Hon'ble Court that as a result of the amendment to Rule 69 of the Drugs & Cosmetics Rules, 1945, each and every state government and union territory administration may now issue licences to pharmaceutical manufacturers operating from within their respective jurisdiction. As a result, there are a total of 36 different State Licensing Authorities (SLAs) which are authorised to issue manufacturing licences for generic drugs. [However 'new drugs' as defined in Rule 122E of the Drugs & Cosmetics Rules, 1945 still require prior approval from the Central Licensing Authority (CLA) which is the DCGI.] Once a licence is issued in one state, the pharmaceutical drugs manufactured as a result of such a licence can, *de facto*, then be sold across the country in all states. If and when a drug, manufactured in one state, is detected to be Not-of-Standard Quality (NSQ) in a different state, the Drug Inspector in such state may initiate prosecution against the licensee but will not have the power to suspend or cancel the manufacturing licence, or even inspect the manufacturing plant, as only the 'home' SLA (which issued the manufacturing licence) can cancel or suspend the licence, or inspect the manufacturing plant. In most cases, the Drug Inspector who has detected the NSQ

sample will write to the SLA who has issued the licence informing them of the violations and requesting for action to be taken against the offending licensee.

26. Predictably, such a cumbersome legal framework with multiple regulators has led to poor co-ordination and often inconsistent application of law. A few of the consequences of having such multiple regulators are listed below:

27. **(i) Different standards of recruitment and training in each state leads to differing standards of enforcement of the law:** Currently each state drugs control department conducts its own recruitment process based on the qualification criteria laid down in the Drugs & Cosmetics Rules, 1945. The recruitment process however is not controlled by the Drugs & Cosmetics Rules and each state may prescribe their own rules to guide the recruitment process. Since the recruitment process is different for each state, the training process is also most likely different. A natural result of such differences is that drug inspectors in different states enforce the provisions of the law differently. This conclusion is easily supported by a comparison of criminal complaints filed in Tamil Nadu and Andhra Pradesh by the drug inspectors of the respective states under the Drugs & Cosmetics Act, 1940. From a *prima facie*reading of the complaints it is obvious that the drug inspectors from

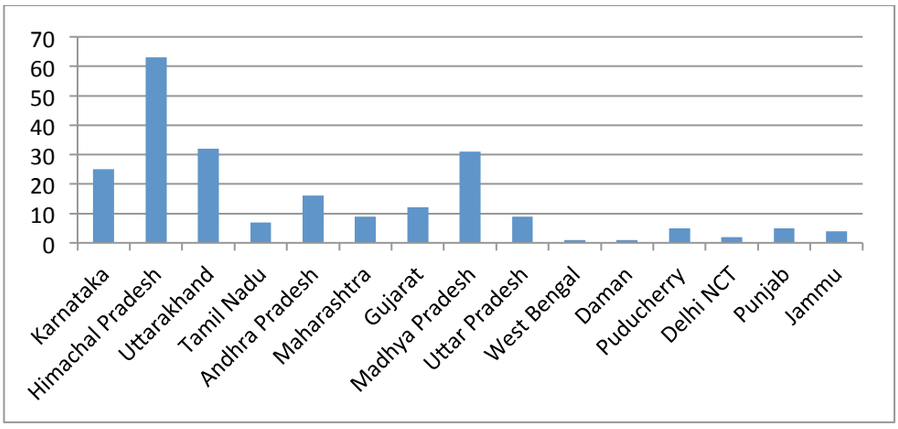
Tamil Nadu are better trained in investigations than drug inspectors in Andhra Pradesh.

28. **(ii) Poor inter-state co-ordination on the issue of drug recalls:** Currently, each state draws drug samples from the market for quality testing and if a sample fails such quality testing the State Drugs Controller may order the manufacturer in question to withdraw the drug from the market. However such information is rarely shared with other state regulators as a result of which a NSQ batch withdrawn from one state can be sold in another state. In a recent interview to the press, (Amend D&C Act to make manufacturers accountable for prompt recalling of NSQ drugs from market: Kerala deputy DC, *Pharmabiz* October 12, 2015) the Deputy Drug Controller of Kerala publicly voiced concerns that the drugs ordered to be recalled from one state were being sold in another state.

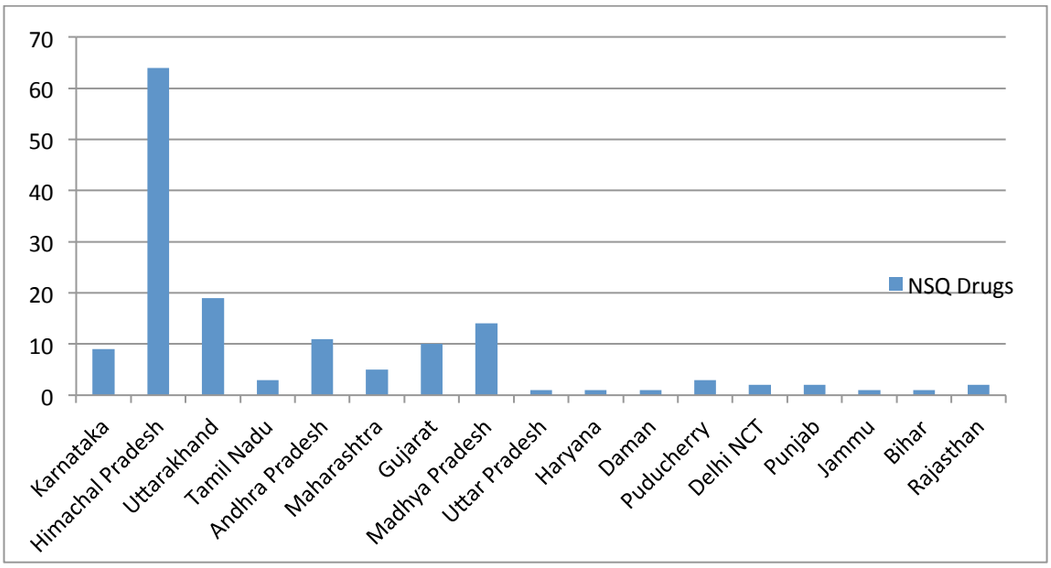
29. **(iii) Different states suspends licence suspensions under Rule 85-I for different time periods:** An illustrative example of such inconsistent application of the law is the significant difference in the duration for which each state suspends a manufacturing licence as punishment for manufacturing NSQ drugs. In order to establish this difference in the duration for which licences are suspended, the petitioner through his advocate procured, under the RTI

Act, copies of the Register of NSQ drugs maintained by the Karnataka Drugs Control Department (KDCD). This Register contains details of all the NSQ drugs detected by the KDCD within the state of Karnataka and the action taken against them. Since a majority of the NSQ drugs were actually being manufactured outside the state, the KDCD did not have the power to suspend or cancel licences for most of these manufacturers.

30. Below is a graphical representation of the states (i.e. the state which issued the manufacturing licence) from which the KDCD detected NSQ drugs in the year 2012-13.



31. Below is another graphical representation of the states from which the KDCD detected NSQ drugs in the year 2011-12.



32. The two states accounting for the largest number of manufacturers of NSQ drugs every year in Karnataka are Himachal Pradesh and Uttarakhand, with Madhya Pradesh coming a close third. In such cases, where manufacturers of NSQ drugs are located outside the state, the KDCD would communicate with the State Licensing Authority (SLA) located in the home state of the manufacturer where the NSQ drug was manufactured. In response, the 'home' SLA would suspend or cancel the licence of the manufacturer and inform the KDCDA of the duration for which the licence was suspended. From the details contained in the Registers, it is quite obvious that there is no consistency amongst different states in the manner in which licences are suspended. For example while states like Himachal Pradesh, suspend licences from anywhere between 15 days to 3 months, states like Uttarakhand would suspend

licences for a mere 20 days while a state like Gujarat would suspend a licence for just 1 day. This is only one example of how the multiplicity of licensing authorities is causing the inconsistent application of the law across the country.

33. It is humbly submitted to this Hon'ble Court that the problem regarding lack of uniformity and consistency in application of the Drugs & Cosmetics Act, 1945 because of poor inter-state co-operation and multiplicity of state licensing authorities, has been pointed out by multiple expert committee reports and parliamentary committee reports.

34. The Report of 'The Expert Committee on a Comprehensive Examination of Drug Regulatory Issues, Including the Problem of Spurious Drugs' (2003) commissioned by the Ministry of Health & Family Welfare and headed by eminent scientist Dr. R. A. Mashelkar, had come to a similar conclusion. In its report the Expert Committee had stated:

"*The Committee observed that in India, because of numerous licensing authorities (State/UT's), the implementation of drugs laws has been weak and non-uniform even after 56 years of enforcement. It is well established that the regulatory infrastructure in many States is below par, while it is functioning better in some. This has resulted in lack of adequate confidence among the consumers and level playing field for industry. The Committee observed that the issue of non-uniformity of enforcement at the state level was serious and needs to be addressed immediately. The Committee records that there*

should have been a single agency to regulate the manufacture and quality control of drugs in the country and that it should be done centrally."

True and correct copy of the Expert Committee Report, 2003 is annexed herewith as **ANNEXURE P-4**.

35. This expert committee had also noted that several prior expert committees such as the Hathi Committee Report (1978), the National Human Rights Commission (NHRC) Report (1999), The Estimates Committee of the 7th Lok Sabha (1983-84) had all come to similar conclusions that licensing had to be centralised under a national regulator in order to achieve more efficient enforcement of the Drugs & Cosmetics Act, 1940. In its final conclusion, the Committee had recommended that all licensing activities be centralised. The Committee's conclusion is reproduced as follows:

"*All the members of the Committee concurred with the suggestion of licensing of drug manufacturing units by a central authority, excepting for one member, namely the Commissioner, Food & Drug Administration, Government of Maharashtra, who gave a note of dissent. This was duly taken note of."*

36. Acting on the recommendations of the Expert Committee, the Ministry of Health & Family Welfare introduced the Drugs & Cosmetics (Amendment) Bill, 2007 in Parliament. In the 'Statements of Objects & Reasons' appended to the Bill, the Government had explained that the Bill sought to centralise drug licensing in India on the basis of the

recommendations by Dr.Mashelkar. In pertinent part, the 'Statement of Objects & Reasons' stated the following:

"*The Committee, inter alia, recommended setting up of a Central Drugs Authority reporting directly to the Ministry of Health and Family Welfare and a system of centralised licensing. The Central Government considered the recommendations of the Committee and proposes to make amendments in the Act, in order to facilitate setting up of a Central Drugs Authority and introduction of Centralised licensing for manufacture of drugs in pursuance of the said recommendations."*

True and correct copy of the Drugs (Amendment) Bill, 2007 is annexed herewith as **ANNEXURE P-5**.

37. This Bill was referred to the Parliamentary Standing Committee on Health and Family Welfare for examination. In its 30th Report, this Standing Committee noted that during its interactions with 'drug manufacturers' associations, State Drug Controllers' associations, experts and also State Govts.', a majority of them opposed the centralisation of drug licensing. The Standing Committee however expressed its agreement with the Mashelkar Committee report on this issue of centralising drug licensing activities (Para 9.22, 9.23). The relevant paragraphs of the Committee's reports are excerpted below:

9.22 In this regard, the Committee takes note of the specific recommendation for licensing of drug manufacturing units by the Central Drug Administration made by the Mashelkar Committee after a detailed analysis of ground realities,

recommendations of earlier expert Committees and views of all the stakeholders. Issue of non-uniformity of enforcement at the State level with regard to quality control of drugs was the main factor behind such a recommendation made by all the bodies like NRHC, Hathi Committee, Estimates Committee (Seventh Lok Sabha) and Mashelkar Committee. Committee's attention has been drawn by the guiding principle driving this suggestion, aptly summarized in para 33 of the Hathi Committee Report quoted below:-

"quality control of products manufactured anywhere in India was not solely the responsibility of the state in which the manufacturing unit is located, since the product is sold all over the country. If a unit in one state was allowed to manufacture and market a product of substandard quality, this would nullify the measures taken by other States. It was essential that the Central Government should assume responsibility for ensuring statutory enforcement and control over the manufacture of drugs all over the country."

9.23 The Committee agrees with the assessment made by all the earlier Committees that there was an urgent need for having a word class drug regulatory system in the country which can effectively handle the health concerns of one sixth of humanity. The Committee can only reiterate that wherever the health and safety of life of the people is concerned, cutting across regional/State specific interests/issues, the emphasis should be protecting the same.

True and correct copy of the 30th Report of the Department Related Parliamentary Standing Committee on Health & Family Welfare, 2008 is annexed herewith as **ANNEXURE P-6**.

38. This Bill was never enacted into law by Parliament. In the year 2013, the Ministry of Health and Family Welfare introduced the Drugs & Cosmetics (Amendment) Bill, 2013. Amongst other reforms, this Bill too sought to centralise licensing activities. In the 'Statement of Objects & Reasons' it was explained that the earlier Bill in 2007 was withdrawn to make it more comprehensive and that "The new Bill contains, inter alia, a revised approach to the centralised licensing, in respect of seventeen categories of very critical drugs included in the proposed Third Schedule to the Act…". When this Bill was referred to the Parliamentary Standing Committee on Health and Family Welfare, the committee in its 79th report did not object to the centralisation of licensing activities, despite hearing several objections from industry organisations. The Committee only asked the Government to reconsider including 2 categories from the 17 categories mentioned in the proposed Third Schedule. In pertinent part the Committee stated the following:

During the course of oral evidence before the Committee strong objections have been raised on Central Licensing of 17 Categories of Drugs as mentioned in the proposed IIIrd Schedule in General and especially 2 categories of Drugs namely Betalactums and Cephalosporins Antibiotics and Parenteral Preparations. The Committee recommends that in view of the concerns received from various stakeholders on the centralized licensing of Betalactums and

Cephalosporins Antibiotics and Parenteral Preparations, they may be reconsidered.

True and correct copy of the Drugs (Amendment) Bill, 2013 is annexed herewith as **ANNEXURE P-7**.

True and correct copy of the 79th Report of the Department Related Parliamentary Standing Committee on Health & Family Welfare, 2013 is annexed herewith as **ANNEXURE P-8**.

39. The Committee however criticised other aspects of the Bill as a result of which the Government never pushed the Bill through Parliament.

40. **As per Disclosure requirement under Order XXXVIII of the Supreme Court Rules, 2013 for petitioners in PIL cases, the following are the details of the Petitioner;**

A. **Name:** Dinesh Singh Thakur

B. **Postal Address:**
103 A, Thomas Prabhu Reliance Complex,
First floor, 3-6-278, Opp. Dr. P.Shiva Reddy Eye Hospital
Himayatnagar, Hyderabad Pin 500029
Telangana State

C. **Annual Income**: The petitioner received a payment of $48 million dollars in the year 2013 for being the whistle-blower in the case of *United States ex rel. Dinesh S. Thakur v. Ranbaxy USA Inc., et. al.,* Civil Action No. 1:07-00962-JFM (D. Md.) The petitioner, through his company Medassure Global Compliance Corporation, advises, pharmaceutical companies,international NGOs and aid agencies on issues relating to quality of medicines.

D. **Email:** dinesh.thakur@medassurecompliance.com

E. **Phone number:** +91.9818402188

F. **The nature and extent of personal interest, if any, of the petitioner(s):** None

G. **Details regarding any civil, criminal, or revenue litigation, involving the petitioner or any of the petitioners, which has or could have a legal nexus with the issue(s) involved in the Public Interest Litigation:**The petitioner was a plaintiff in the case of*United States ex rel. Dinesh S. Thakur v. Ranbaxy USA Inc., et. al.,* Civil Action No. 1:07-00962-JFM (D. Md.). This litigation before the United States District Court in Maryland has been concluded after a settlement between all parties and a copy of the settlement agreement is annexed herewith. The petitioner received a payment of $48 million dollars from the penalty of US $500 million dollars imposed on Ranbaxy in the aforementioned case. This litigation pertains only to one of the issues raised in this petition, which is the failure of the Indian Government to adequately investigate Ranbaxy for failure to comply with quality standards. There are no other litigations in which the petitioner is involved against the pharmaceutical industry.

H. **Whether the concerned government authority was moved for relief sought in the petition and if so, with what result:** The petitioner on September 17, 2014 met

the then Union Minister for Health Dr. Harsh Vardhan with a representation to urgently improve the quality of medicine in India and reform the CDSCO. A written letter to this effect was sent to the Minister on October 19, 2014. The Minister never replied to the petitioner. A copy of letter sent by the Petitioner to the Union Minister of Health with a representation for improving quality of medicine in India is annexed herewith and marked as **ANNEXURE P-9.**

I. The petitioner also attempted to meet the Chairperson of the Quality Council of India (QCI) but was unsuccessful.

J. **The facts constituting the cause of action:** Are elaborated in PARAS I, 5 & 6 and III of the Petition.

K. **The nature of injury caused or likely to be caused to the public:** Are elaborated in PARAS I, 5 & 6 and III of the Petition

41. The Petitioner submits that the details of his PAN Number are not disclosed in the Petition and an application for exemption from disclosing the same in the Petition is filed along with this Writ Petition.

42. The Petitioner states that no other similar petition has been filed by him before this Hon'ble Court or any High Court or any other Forum.

43. **GROUNDS**

The petitioner submits that Rule 69 of the Drugs & Cosmetics Rules, 1945 and its associated rules are *ultra*

vires Section 33(2)(e) of the Drugs & Cosmetics Act, 1940 on the following grounds:

(A)A simple literal interpretation of the phrase "*the authority empowered to issue the same"* as used in S. 33(2)(e) of the Drugs & Cosmetics Act, 1940 indicates that the legislature wanted the Central Government to appoint only one authority to issue licences for all manufacturing activities. However Rule 69, as notified by the Central Government, states that the licensing authority shall be appointed by the State Government (which is defined in the legislation to include "Union Territories"). This has resulted in India having not 1 but 36 different regulators across the country which can license the manufacture of drugs. Thus Rule 69 goes beyond the ambit of Section 33(2)(e) of the Act and is unconstitutional because a Rule cannot go against the intent or language of the parent statute. The Supreme Court has reiterated this rule in several cases such as *State of Tamil Nadu & Anr.* v. *P. Krishnamurthy and Ors.* AIR2006SC1622; *Supreme Court Employees Welfare Association* v. *Union of India*(1989)4SCC187.

(B) A simple literal interpretation of S. 33(2)(e) suggests that the Central Government is required to appoint the licensing authority by itself rather than the sub-delegate this power to the State Government as has been done presently in Rule 69. This rule of statutory interpretation is well captured in the

Latin maxim of *delegatus non podest delegare* which means that an authority to whom power has been delegated by a statute cannot further sub-delegate that said power to another authority unless the language of the authority expressly allows for such a delegation of powers. The logic behind this maxim is simple: a delgatee of power cannot act beyond the scope of power delegated to it. This rule against the sub-delegation of power, unless it has expressly been allowed for in the text of the statute, has been reiterated time and again by the Hon'ble Supreme Court of India in the cases of *Sahni Silk Mills Pvt. Ltd.* v. *ESI Corp.*1994 SCC (5) 346and*A.K. Roy &Anr.*v. *State of Punjab* (1986 SCR (3) 961).Since Section 33(2)(e) delegates the power of appointing the licensing authority to only the Central Government, it is legally impermissible for the Central Government to further sub-delegate this power to the State Governments without the language of the statute expressly permitting such further sub-delegation. Rule 69 is therefore expressly unconstitutional and *ultra vires* the governing provision of Section 33(2)(e).

(C) The legislative history of Section 33(1), especially the replacing of the word 'provincial government' with the word 'central government' by the Drugs (Amendment) Act, 1955; is a clear indication that Parliament intended to shift all

regulation of domestic manufacturing from the Provincial Governments to the Central Government.

(D) The legislative history of Section 33 as can be understood from the 'Statement of Objects & Reasons' to the Drugs Bill, 1955, the Statement of the Minister in both the Lok Sabha and Rajya Sabha, and also the 'Statement of Objects & Reasons to the Drugs Bill, 1960 conclusively establishes that the legislative intent behind the Drugs (Amendment) Act, 1955 was to ensure centralisation of licensing activities with one authority functioning under the Central Government.

PRAYER

In the premises set forth above, the Petitioner prays that this Hon'ble Court may be pleased to:

(a) Pass an order declaring Rule 69 of the Drugs & Cosmetics Rules, 1945 to be *ultra vires* the provisions of Section 33(2)(e) of the Drugs & Cosmetics Act, 1940;

(b) Pass an order declaring Rule 69A, 70, 70A, 73, 73A, 75 & 75A of the Drugs & Cosmetics Rules, 1945 of the Drugs & Cosmetics Rules, 1945 to be *ultra vires* the provisions of Section 33(2)(e) of the Drugs & Cosmetics Act, 1940;

(c) To pass any other order or direction that this Hon'ble Court deems fit in the interests of justice, equity and good conscience;

DRAWN BY: FILED BY:

PRASHANT REDDY T.
ADVOCATE (ANITHA SHENOY)
ADVOCATE FOR THE PETITIONER
ADVOCATE ON THE RECORD

New Delhi
Dated: 28.01.2016

IN THE SUPREME COURT OF INDIA

(CIVIL ORIGINAL JURISDICTION)

WRIT PETITION (CIVIL) NO. OF 2016

IN THE MATTER OF: -

Dinesh S. Thakur ….. PETITIONER

VERSUS

Union of India ….. RESPONDENT

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11.	**ANNEXURE P-8** True and correct copy of the 79th Report of the Department Related Parliamentary Standing Committee on Health & Family Welfare, 2013	
12.	**ANNEXURE P-9.** A copy of letter sent by the Petitioner to the Union Minister of Health with a representation for improving quality of medicine in India dated 19.10.2014	
13.	Letter	