

**SC JUDGMENT ON FREEBIES : A HIT TO PHARMA HONCOS :
A BIG REFORM FOR PUBLIC GOOD**

Justice Dr. Vineet Kothari

Former Acting Chief Justice of Gujarat & Madras High Court

And Judge of Rajasthan & Karnataka High Court.

The judgement delivered by a Bench of Apex Court in the case of Apex Laboratories on Palindrome Date 22.02.2022, a coincidence, has the same effect – you read the entire judgement from beginning to end or end to beginning – a Huge Public Good.

What appears on the face to be resolving a simple Income tax issue, the Court not only disallowed the expenditure of Rs.4.72 crores to be deducted from its business profits u/s 37 of the Act, which was incurred by the company on Freebies like Conference Expenses, Hospitality, Free TVs, Fridges, Laptops etc. to Doctors and Medical Practitioners holding it to be an expenditure prohibited by law or Regulations framed by the Medical Council of India and was therefore hit by Explanation of S.37, in effect, this judgement will go a long way as Law Declared binding under Art. 141 of the Constitution of India as a Social Engineering Tool by financial disincentive for checking unethical and illegal practices in pharma sector which has become so “ out of reach for common man “ by its spiraling costs, which entire world saw more painfully in Covid period of last two years. The Pharma Honchos, Hospital owners and Doctors became Millionaires and Billionaires overnight while death was dancing at most of the doorsteps.

Amendment of Law by Finance Bill, 2022

Though the Finance Bill 2022 presented by Finance Minister Ms. Nirmala Sitharaman seeks to amend s.37 further by adding Explanation 3 to provide that the Expenditure prohibited by law as given in Explanation 1 to that provision will include such expenditure to provide any benefit or perquisite to a person for whom the governing code of conduct provides it as a violation of such code of conduct and perhaps this amendment puts this controversy beyond the pale of doubt even for future.

Judgement is for Prior Period

But the aforesaid Judgement in the case of Apex Laboratories is here not only to settle the dispute, but to generate a more wholesome debate on how the uncontrolled and unruly horse of medical health care can be reined in to make it a real affordable service to the Human Race rather than profiteering by the fear psychosis the monopolistic regime generates and the blind faith of the illiterates in medical terminology, which we all are, except the medical graduates, have in Gods read Doctors.

Repelling the contention raised on behalf of Company by Mr. S. Ganesh, Senior Counsel, the learned Justice S. Ravindra Bhat, the author of the Judgement of the Bench headed by Justice U.U. Lalit, said that the Pharmaceutical companies have misused a legislative gap to actively perpetuate the commission of an offence of giving freebies to doctors to promote their brands, even though the medical practitioners were prohibited in law framed by MCI. In this case company was promoting **ZENCOVIT**, a health supplement.

Outreach of the Judgement

Beautifully doing the social engineering, the learned Judge said that in the process of interpretation of law, it is the responsibility of the Court to discern the social purpose which the specific provision subserves. The cold letter of the laws is not an abstract exercise in semantics which (law) practitioners are wont to indulge in. So viewed the law being interpreted in the case on hand, has berthed various ideas such as implied conditions, unspelt but entirely logical and reasonable obligations implied limitations etc. The process of continuing evolution, refinement and assimilation of these concepts into binding norms injects vitality and dynamism to the statutory provisions. Without dynamism and contextualization, law becomes irrelevant and stale. Quoting Justice Oliver Holmes, the Bench observed, “ A word is not a crystal, transparent and unchanged; it is the skin of a living thought and may vary greatly in colour and content according to the circumstances and the time in which it is used.”

Precedents Thread Bared

Upholding the CBDT Circular dt. 1.8.2012 and applying to the case, the Court also quoted and relied upon Regulation 6.8 of Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 framed under Medical Council Act, 1956 , now repealed and by substituted by National Medical Commission Act, 2019, the Court distinguished the earlier judgments in the case of Quereshi (2007) 2 SCC 759 where court allowed to deduct the cost of heroin seized as business loss and that of MP High Court in the case of KM Jain (2011) 4 MPLJ 691 where ransom money paid to kidnappers for release of employee was allowed as business expenditure in the hands of Employer, the court held that in both these cases, the assessee was not a wilful participant in any offence

or illegal activity prohibited by law. While overruling the Income Tax Tribunal's view in the case of PHL Pharma (2017) and Max Hospital (2014) ILR 1 P. 620, the court held that Regulations 2002 did apply to pharma companies also and they could not be allowed to perpetuate illegality of violations of norms by the Doctors. Invoking the principle of implied condition, the Court relied upon the precedents in the case of P.V. Narsimha Rao (1998) 4 SCC 626 under Prevention of Corruption Act, and Jaml Uddin Ahmad (2003) 4 SCC 257 under Representation of People Act.

Relationship of Doctor & Patient

Emphasizing upon the fiduciary relationship of a Doctor and the Patient, the Court noted with pain that a Doctor's prescription is considered as final word on medication by the Patient even if the cost of such medication is unaffordable and where such is the trust reposed in Doctors, if such prescriptions can be manipulated by the lure of Freebies, how much immoral it would be. The court was conscious that the cost of such Freebies is factored in the cost of medicines sold driving up their prices and which creates a perpetual publicly injurious cycle. This fact was taken note of even by the Parliamentary Standing Committee on Health and Family Welfare in its 45th Report dt. 4.8.2010.

USA Law also considered

The court in this elaborate judgement also took note of a Report issued by US Department of Health and Human Services Office called " Savings Available Under Full Generic Substitution of Multiple Source Brand Drugs in Medicare Part D " dt. 23.07.2018 in which it

was stated that the Beneficiaries could have saved over \$600 million in out of pocket payments had they been dispensed generic equivalent drugs. In a previous study by ProPublica titled “ Dollars for Doctors : Now There is Proof : Docs who get Company Cash Tend to Prescribe Brand Name Meds ” dt. 17.03.2016 also similar feelings were echoed. In USA, by the reason of Physician Payment Sunshine Act, 2010 by s. 6002 of the Affordable Care Act, 2010 the law compels the manufacturers of drugs, devices, biologic and medical supplies to report to the Center for Medicare and Medicaid Services on three broad categories of payments or transfers of value such as meals, travel reimbursements and consulting fees. These include expenses borne by manufacturers such as speaker fees, travel, gifts, honoraria, entertainment, charitable contribution, education, grants and research grants etc.

Uncovered Field

Obviously the uncovered field in this judgement and of course it was not the controversy in hand before the court is the sale of medicines at MRP (Maximum Retail Price) . A big scam and underhand dealing happens in pharma world and giving of Freebies is a smaller part of it because drugs are invariably sold at the counter of pharmacist shops at MRP only without a question. This is what makes the medical treatment, a service to humanity a scam of gigantic proportions. Even though Drug Price Control Order and Drugs and Cosmetics Act are there on the statute book, hardly any action to keep the sale price of medicines under control by due and proper investigation into their so called R& D costs and keeping their profit margins within a prescribed limit is seen.

Need to amend the Drug Pricing Law

One fails to understand why the law cannot be amended to compel the manufacturer of drugs to sell at the verified genuine cost plus reasonable profit margin for each product by bringing even the manufacturers, foreign or domestic, under the control of MCI or any other equivalent body like ICAI (Institute of Chartered Accountants of India) or Institute of Cost and Management Accountants of India and at that too at a uniform rate through out the country and the classified life saving drugs may be sold at cost only or even at subsidized rates.

Signing off Conclusions

No body is against a reasonable profit to be earned even by pharma industry but the urgent need is there to check the loot by them based on the fear in this industry which is created in the ignorant masses by the qualified Doctors and aggressive Advertisements, who are driven or rather overdriven by the Drug Manufacturers by distribution of their largess to their door steps – call that Freebies or Bribe -what you want.

Keep the Hope Alive : Future Developments of Law

This Judgment will also go afar and should be debated and applied further for other unethical practices and expenditure out of public funds, which can be and should be discouraged through financial tools like Income Tax provisions for disallowing such expenditure on the one hand and taxing the same as perquisites or taxable income in the hands of the recipients viz. assurances and declarations in

election campaigns by Political parties of giving of free laptops, electricity, food grains, loan waivers etc. and then actually doing so out of tax payers' money on forming the Government by garnering votes on such lollypops.