Ethics of expert opinion and the observations of the department-related parliamentary standing committee on the CDSCO

Amar Jesani

Editor, Indian Journal of Medical Ethics (www.ijme.in), Trustee, Anusandhan Trust, Mumbai, Maharashtra, India

On May 8, 2012, the Department Related Parliamentary Standing Committee (henceforth Committee) presented to the Parliament its 59th report on the functioning of Central Drugs Standard Control Organization (CDSCO) in the Ministry of Health and Family Welfare (MoHFW) (henceforth DRPSC Report).[1]With the media highlighting its findings, there was a public outcry on the way the country's drugs regulator is functioning. At a time when the credibility of Parliamentary politicians is at the lowest ebb, report provided some hope as members of the parliament constituting the committee made some very incisive comments and recommendations to improve the regulatory work of the CDSCO.

The findings contained in the 59th DRPSC report are well known, and we have dealt with some of them elsewhere.[2]To summarize, it found that (a) the mission of drugs regulator in India was contrary to the universally acknowledged mission of protecting consumers and public health; instead it looked at its job as facilitator of the pharmaceutical industry, to meet its aspiration, demand and requirements; (b) the CDSCO has abysmally inadequate human and material resources, no modern infrastructure and poor expertise to discharge its regulatory function; (c) the CDSCO has pursued highly questionable – sometimes irregular and unlawful – practices in drugs approval and above all, (d) there was evidence of collusion between industry, regulator and experts, which in other words means the capture of the regulatory apparatus by those it is meant to regulate.

Access this article online	
Quick Response Code:	Website: www.jpharmacol.com
	DOI: 10.4103/0976-500X.103684

Being a powerful Parliamentary Committee, its members could access all documents, pick up records using randomized sampling method,analyze them scientifically, and could summon officials of the CSDCO and the Health Ministry to testify. Interestingly, the report systematically marshals evidence to arrive at its conclusions, thus, making it a very formidable document to refute. India has huge pharmaceutical industry, it exports third of its pharmaceutical production and has visible presence in the international market. Besides, since 2005 when the Schedule Y of the Drugs and Cosmetics Act was amended allowing concurrent drugs clinical trials for Phases II and III, India has become important destination of clinical trials outsourced by the international companies, with Indian companies and research organizations also significantly increasing their clinical research for introduction of new drugs. With such massive industry and activities in the field of drugs, Indian people can ignore the findings of this committee only at its own peril.

Medical expert opinion for waiver of clinical trials

Of the wide range of issues raised by this report, we focus on two important issues about the involvement of doctors as experts recommending new drugs for introduction in Indian market without clinical trials, and competence of the CDSCO officials in scientifically assessing such recommendations. Both of them put together raise some serious concerns about the ethics of providing expert opinion.

The Committee found that from Jan 2008 to October 2010 (a period of 34 months), the CDSCO had approved 33

Address for correspondence:
Amar Jesani, Sai Ashray, Aaram Society Road, Vakola, Santacruz (East), Mumbai, Maharashtra, India.
E-mail: amar.jesani@gmail.com

new drugs without conducting clinical trials, or almost one drug per month (page 28, 29).[1] Instead of clinical trials, the CDSCO had relied on the expert opinion provided by select few doctors to take such legal decisions. The committee randomly selected nine such drugs and scrutinized the expert opinions on them provided by doctors. The written opinions of the doctors available with the CDSCO are annexed to the report, thus making them publicly available. Indeed, this is for the first time that such medical opinions have been made public for the other experts in the profession to openly debate the merit of the opinions. The Committee made the following observations on them:

"A review of the opinions submitted by the experts on various drugs shows that an overwhelming majority are recommendations based on personal perception without giving any hard scientific evidence or data. Such opinions are of extremely limited value and merely a formality. Still worse, there is adequate documentary evidence to come to the conclusion that many opinions were actually written by the invisible hands of drug manufacturers and experts merely obliged by putting their signatures" (page 33).[1]

This is a very harsh assessment, and the minimum those experts should do is to seriously defend both the forms and contents of their opinions in scientific journal. But we are not aware that they have made such efforts. A reason for that not happening so far is perhaps that while ostensibly each opinion was written in response to the request made by the Drug Controller General of India (DCGI), the Committee found enough prima facie evidence to allege that they were collected and delivered to the CDSCO office by the interested parties (the agents of the pharmaceutical companies which had applied for the waiver of clinical trials), and worse still, that some of them were perhaps not even written by those doctors. At least one doctor admitted to the media that the expert opinion was sought by a "private party".[3] While most of them have denied any corruption and any wrong doing, they are not able to explain why in many cases the wordings of opinion are almost same if not identical, including some typographical errors. Why in some cases evidence exists to show that the expert opinion was never mailed by the doctors to the CDSCO, but collected and delivered by the interested parties? Instead of providing clear evidence that the Committee's assessment is wrong, at least one doctor tried to use the profession's monopolistic control of medicine in an intimidating way - "If such observations are made against doctors then no one will come forward to give their advice and honest opinion".[3]

Ethics of providing expert opinion

Doctors are often called upon to provide expert opinion or testimony in the court of law. As under-graduate medical students we learn in the forensic medicine about the ethical and legal responsibilities of the expert witness. However, a clinician, not used to regularly testifying in the court of law as a forensic doctor does, sometimes overlook that learning. Since the CDSCO has rarely, if ever, shown its harsh face of strict regulator and instead only worked as facilitator of the pharmaceutical companies and doctors, one may tend to forget that it is a legally constituted authority and could use its power to punish in the same way the court does. Like in the case of court judgment, the decision taken by the CDSCO on the basis of the expert opinion can have serious consequences of causing harm to many due to introduction of an untested drug, or saving lives by making a drug available in emergency situation or in epidemic.

Perhaps in writing opinion it is assumed that since one is not appearing before the court and giving opinion under the oath, there was nothing to worry about getting punished by law. This shows that care is taken to safeguard from law, but the ethics are not cared for at all. The law is minimal ethics, but in our country, it has become maximum ethics, that also only after efforts to use loopholes in the law not to abide by it have failed. This is travesty of both the law and ethics. In any case, the law may still catch up. The Committee has recommended that "many actions by experts listed above are clearly unethical and may be in violation of the Code of Ethics of the Medical Council of India applicable to doctors. Hence the matter should be referred to MCI for necessary follow up and action. In addition, in the case of government employed doctors, the matter must also be taken up with medical colleges/hospital authorities for suitable action" (page 36).[1]

Indeed, instead of being brazen about it, the profession should use this episode to learn and put its house in order. In the developed countries in the past, there are instances when the licenses or registrations for medical practice were revoked due to unethical conduct in medical testimony.[4,5] While the best solution is reform of individuals by making them to learn the ethical conduct in provision of expert opinion, some punishment for transgressing ethics as deterrent is a must in order to make the professionals understand the seriousness of ethics.

In order to learn, about the ethical conduct in the provision of expert testimony or witness, one doesn't have to go too far as much of that has been codified. For instance, following the judgment in the well-known "Ikarian Reefer" civil suite for compensation in a non-medical case that was relied upon the expert evidence, the UK in 1998 incorporated ethical standards for the expert witness in its Civil Procedure Rules.[4]They also have lots of relevance for understanding the ethical standards for the medical opinion given by the doctors to assist the legal authorities to take decisions in cases such as marketing approval of drugs. One only needs to look at these standards to appreciate why the Committee was so worked up about the ethics of the expert doctors. Some of those standards used by the UK are:[4]

- "Expert evidence presented to the court should be,and should be seen to be, the independent product of the expert uninfluenced by the exigencies of litigation";
- "An expert witness should provide independent assistance to the court by way of objective and unbiased opinion to matters within this expertise".
- "An expert witness should never assume the role of an advocate";
- "An expert witness should state the fact or assumptions on which his opinion is based";
- "An expert witness should not omit to consider material facts which could detract from his concluded opinion";
- "An expert witness should make it clear when a particular question or issue falls outside his expertise";
- "If an expert's opinion is not properly researched because he considers that insufficient data are available, then this must be stated";
- "If, after exchange of reports, an expert changes his view on a material matter, having read the other side's expert's report or for any other reason, such change ofview should be communicated to the other side without delay, and when appropriate, to the court".

Of course, with the report of the committee out and in public domain, the doctors who provided the expert opinion in support of the pharmaceutical companies' application to waive clinical trials for their new drugs, have an obligation to provide evidence that the standards as mentioned above were observed.

Lastly, while objectivity and neutrality are the best desirable goals in science, it is well known that the science is not devoid of values. The important issue here is that in those opinion there is inadequate evidence that the values adhered to were for the best interests of the patients and the consumers in general. Instead, the evidence of serious conflict of interests of the experts as their opinions were collected by the interested parties, and in the worst case even written by the interested parties; point towards the predominance of values meant to benefit the industry. The external values and benefits marring the objectivity and the conflict of interests eroding credibility of the science could be countered the best by having high standards of transparency. Many countries are now toughening their laws on the conflict of interests [6] and also make it mandatory for the public authority to make available in the public domain the opinions given by the experts.As the Committee has demanded, our country needs to go in the same direction.

REFERENCES

1. Department related parliamentary standing committee on health and family welfare, 59th Report on The Functioning of Central Drugs Standard Control Organisation (CDSCO), Government of India. Available from:http://164.100.47.5/newcommittee/reports/englishcommittees/committee%20 on %20 health %20 and %20 family %20 welfare/59. pdf. [Last accessed on 2012 May 8].
2. Srinivasan S, Jesani A.Standing committee report on CDSCO: Hard facts confirm an open secret. Indian J Med Ethics2012;9:148-50.
3. Pandey V. "The shocking Medical Scam" DNA 2012. Downloaded from http://www.dnaindia.com/india/report_dna-special-the-shocking-medical-scam_1688378 accessed on 2012 Sep 20.
4. Friston M.Roles and responsibilities of medical expert witnesses. BMJ 2005;331:305-6.
5. Resnik D. "Punishing medical experts for unethical testimony: A step in the right direction or a step too far?"JPhilosSciLaw 2004;4:2004.
6. Butler D. "France tightens conflict rules".Nature 2011;478:169.

How to cite this article: Jesani A. Ethics of expert opinion and the observations of the department-related parliamentary standing committee on the CDSCO. J Pharmacol Pharmacother 2012;3:297-9.
Source of Support: Nil, **Conflict of Interest:** None declared.