

Folk Wisdom to Scientific Research

The Curative Powers of *Neem*

○ Paige Passano Talks to Prof. Ranjit Roy Chaudhury

Neem is a widely used tree in India. People all over the country use twigs from its branches for cleaning their teeth. Its leaves, bark, seeds and roots are used for their anti-microbial and several other properties. In rural communities *neem* is used far more extensively because it is easily available there. In fact, a rural *vaid* once told me that he doesn't need to get medicines from any government stock as he has a *neem* tree in his compound and uses it for all sorts of ailments: stomach problems, skin ailments, simple or persistent cough and even for prevention of malaria. As long as there is the *neem* tree, he doesn't worry when the government doesn't supply medicines for his primary health centre. However, *neem* is still not used much in for allopathic medicines. This creates a wide gap between *neem*'s widespread usage as a folk or ayurvedic medicines on the one hand, and its complete non-existence in allopathic medicines.

□ *What are the traditional claims regarding neem's curative powers and potency as a pesticide?*

Neem is definitely the best anti-insect substance we know; it has been traditionally used in the storage of grain and also for preserving woollens from insects. In medicine, it has been used as a tonic; as a treatment for worms; as an antiseptic; and the *neem* oil has been used as an

appetite stimulant. It is believed that, *neem* along with ginger and turmeric, can prevent malaria. *Neem* is also used as an anti-microbial agent. It has anti-bacterial properties, which have actually been proven in laboratory tests. Recent work has shown clearly that *neem* has antimicrocidal effect against organisms, such as Chlamydia, which induce reproductive tract infections in women. As a child, after chicken-pox, my first bath was given with *neem* leaves. We use it all the time. However, as a scientist, and a clinical pharmacologist, I need more rigorous evidence from clinical trials before I can vouch for its efficacy, and I regret to say, these clinical trials have not yet taken place for *neem* and that is why allopathic hospitals all over the

country are not using it. The allopathic-trained doctors want evidence. So to summarize: as a human being, as an Indian, and as a person living in this country, I accept the claims made for *neem*. As a scientist and as a person who is concerned with regulating drug use in the country, I cannot accept folklore, anecdotes; or belief values. I need hard clinical trials and these have not yet been done.

In fact, Indian scientists have done a good amount of non-clinical experimental work on *neem*. They have clearly shown in the laboratory that it is anti-bacterial. This means that it could be used as an anti-septic agent; they have clearly shown that it is effective against liver diseases in animals; they have shown that it is effective against malaria. These animal experiments have to be repeated on human beings through properly controlled clinical trials where one group of patients get *neem* and the other group does not get anything; then a clear effect is shown. When that is demonstrated, *neem* is likely to be accepted in allopathic medicine.

The truth is that the Indian research is not being done with an orientation to develop products. I would say, 80 percent of our research in universities and research centres is being done solely for providing thesis material for students completing their post-graduate



Dr. Ranjit Roy Chaudhury

studies. A medicinal plant has always been a fertile area for carrying out research. *Neem* is one of those plants, *haldi* (turmeric) is another. So, they pick out something that is known to possess a certain quality, and they repeat the trials on animals with extracts that the chemist takes out, and finally, the pharmacologist or biologist tests. The person gets a thesis, the professor gets a paper on it and that is the end of the matter. This has been the bane of all of our researches on medicinal plants. Hundreds and thousands of papers all over the country have provided leads which should have been taken to carry out human testing. But since we don't do the job, these leads are being taken to the West. We are content merely with our research, our papers, our thesis, and our post-graduate degrees.

□ *Why do you think there is such a disinterest amongst Indian scientists and institutions to pursue research further for commercial applications?*

One has to have a historical perspective on this. When I was a professor of pharmacology at a post-graduate institute of medical education research, we did a lot of work on medicinal plants, but we never had the industrial application point of view in mind. We grew up in a tradition where research was free. Anybody could come and look at the research we were doing, could take the results and use them for further work. That was the tradition we grew up in. Today, research has become product oriented, directed towards patent development and intellectual protection of property rights. That is a different field. Also, we as professors, do not have the background to organise funding or the multi-disciplinary expertise it takes

to convert a research finding into a drug. That is a totally different ball-game. I don't think, even now, our government has understood the importance of participating in the new patents regime. That's why we are not able to transfer these findings into commercially viable products.

□ *Are we now moving in the direction of patenting neem products?*

After the great controversy when the Larson and Margot Company and Grace Company patented *neem*, people in India woke up and said, "look, *neem* has been with us for hundreds of years, how come someone else has patented it?" Then, some action was taken. Similarly some five years ago, I published a paper in *The Asian Age* with a big headline: "*Haldi* should be patented in India." Nothing happened for two years thereafter. Suddenly, there was another frenzy over *haldi* being patented in America. We have to change our mind-set. Our younger scientists have to be product oriented. When you go into product development, you go from a 5 lakh grant into a multi-million dollar program. Such a program can only be possible by a very large pharmaceutical company and some support from the government. I don't think the government alone can do it. Even pharmaceutical companies are merging because they are finding it difficult to develop new drugs on their own.

□ *Has the Indian government provided any incentive to pursue the development of commercial applications of neem or other putative medicinal plants?*

Yes, they are trying. They are trying to induce scientists to work with industry. The Central Drug Research Institute at Lucknow is one

such institute, but their main effort is on synthetic drugs. One must realize that if one wants to go through the regulatory pathway for bringing out plant products, it is a long, hard, and expensive journey. You have to do toxicology studies, long-term studies, short-term studies, teratogenesis (studies if you give it to a pregnant woman, "deformed children are not born). Then you have to perform several phases of clinical trials. So, when a plant product is released after all of this, we know that it is safe and effective.

On the other hand, our regulatory agencies have been very lax with regards to Ayurvedic medicines. These medicines do not have to meet any such scientific requirement. Therefore, people are taking herbal medicines straight to the masses through the Ayurvedic route, avoiding the clinical trial route that has been set up for allopathic medicines. This can be dangerous. A plant, which is supposed to enhance memory (I shall not mention its name), is being used all over India. There have been no clinical trials proving its effectiveness. Yet, this has gone through minimal regulatory agency while people use it all over India to enhance memory. Children are being given this so that they receive better marks in exams. It is all really farcical. This is where we have to have a dialogue. We have to talk to the ayurvedic and allopathic physicians and also the drug regulators, to see how we can sort all this out. Either it is done the right way, or don't allow allopathic practitioners to use them.

□ *Is there any formal structure in governing the administration of ayurvedic medicines?*

It's a very weak structure. They do not need any evidence that a plant is effective before allowing it to be

put out in the market. You and I can put *tulsi* and *neem* in a mixture and market it for protecting the liver. Whether effective or not, it would go through. This in fact is the real weakness of the present system.

To apply for a license to produce an ayurvedic drug all one has to do is to show evidence of its use being mentioned in some ancient literature. That is all you need to go ahead and market it. But, this is not understood abroad. They read that we have found a memory enhancing substance, and the White House will ask, "what is it?" They have no idea that it's not even registered in this country as an allopathic drug; it's an ayurvedic drug because all the rules have been by passed.

□ *Is there any research being done which would suggest that some neem derivative might be used as a contraceptive?*

The *neem* seed gives an oil that has been clearly reported to be effective in animals. We know that this is effective in rats when the *neem* seed oil is locally instilled (it is not given by mouth). Research is going on in this interesting area of work. But we need more evidence from tests involving sub-human primates (that is, in monkeys) before we can consider it for humans. The main exciting areas for *neem* are: anti-vital, anti-microbial (anti-bacterial), and for contraception. I think these are the areas which need to be pushed. We have also approved phase one clinical trial of a *neem* derived male contraceptive.

Some collaborative work is now being done with French and American institutions on *neem* and other plants for anti-HIV research. It is not easy for foreign institutions to do research on plants, because the plants are here. You have to get the fresh plants and



be certain that it is the right plant and not contaminated or a hybrid. So, the research is being done here, but there is no task force. I would have thought that there would be a national task force for research on *neem* which would respond like the Chinese, who got a lead on an anti-malarial plant, and set up centres all over the country with specific purposes (toxicology, pharmacology, clinical trials, and so on). The Government of India has done this in the field of contraception; I am the chairman of such a task force, but this is for herbal products and,

unfortunately, *neem* is not one of these products.

□ *What is the nature of neem research that is going on in the West?*

It is primarily commercial to test out its anti-viral, anti-HIV, anti-pest properties. They are not doing contraceptive research in *neem* as an enhancer of general well being. *Neem* research began in the West during last ten years only after the anti-insect properties were discovered.

□ *You mentioned earlier that papers that had been produced by*

Indian scientists and graduate students were the source of this interest in neem?

The first paper on the anti-insect properties of *neem* was produced as a report of the Regional Research Laboratory in Farm Sciences which came out in 1968 to 1973. They clearly wrote in that paper that *neem* extract was the most powerful insect-repellant that they have ever tested. Yet, nothing was done with that report. Similarly, there have been other reports as well. But nobody reads them, that's the problem; not even one percent of our science administrators and health managers read scientific journals. How can they be expected to say, "there's a lead," let's go out and follow? No such mechanism exists.

□ *Western multi-nationals have applied, in the US, for patent rights to certain neem products; what is the nature of such products? Are they simple extracts analogous to what has been used historically in India or do they represent complex formulations that could be thought of as substantively new and different from anything produced in India?*

The Western scientists, mainly in the US, have devised a chemical method for stabilizing the property of *neem* for a long time. This has not been done by Indian scientists. They would get the property and use it for testing and that was it. What Grace Company has patented is a method of stabilizing the activities, so you can keep the product on the shelf and the specific effect of the product remains. This is their contribution. Now, whether this contribution of making an unstable preparation stable deserves a patent, (as the US government believes), or whether this is merely a marginal research which does not deserve a patent (like Mira Shiva and

many others think in India) is a point that has to be decided by each person on his/her own.

□ *What is your opinion on this particular issue?*

My opinion is that the Indian scientists did not or could not stabilize this fraction. As far as this stable fraction is concerned, the US scientists should certainly receive credit for it. This does not stop our scientists today from stabilizing other fractions or finding different ways for getting not only national patents, but also international patents (where we would profit throughout the world). We have never thought ourselves capable of getting international patents and, therefore, bringing new drugs to the world and, thereby, profits to our country. This thinking has to come, but we certainly cannot tell the US patent people (as our *swadeshi* lobbyists are trying to do not only for *neem*, but also for *haldi*) that you can't give patent for specific process of stabilising a herbal product. I don't think that is fair.

□ *One of the claims that environmentalists make is that commercial production of neem based products by the Western multi-nationals, particularly where MNCs are interested in obtaining raw materials from India, will have negative effects on its accessibility to Indian bearers of "indigenous knowledge."*

What I think will happen is that if *neem* seed oil is shown to be a good anti-microbial by a Western firm or even an Indian pharmaceutical, that would lead to rise in *neem* seed prices and perhaps even a scarcity for local use. There would be a greater demand for *neem* seeds. But then the question is would the farmers who grow *neem* trees have an additional source of income? If growing *neem* trees

becomes a profitable proposition, farmers are likely to invest in growing more such trees. Since growing a *Neem* tree is not an expensive proposition, we are likely to witness a widespread interest in growing more and more *Neem* trees. Maybe, this is how ordinary farmers and even urban householders would develop a real stake in reforestation. These seeds come for only a very short time, three or four weeks in a year. So, the firm would try to procure as much of seeds as it can.

□ *What sort of implications does such a large-scale commercial production of neem raw materials have on biodiversity?*

We need large-scale production of *neem*, but *neem* produced and grown in different parts of the country have different yields. So, if we want to use *neem* with high yield of the active substance, we have to find out where that high yield is. There is already one project where different plantations of *neem* are being made in different parts of India so as to study quantitative aspects of production. Extensive planting has to take place where *Neem* would provide the best yields. I don't think that will have any adverse biodiversity affect

At the moment, commercial *neem* products include cosmetics, toothpaste, soaps and other *neem* based products. In addition, there are *neem* tonics, *neem* ayurvedic preparations, and these have not adversely affected anyone. However, in the long run, we may find a synthetic compound from *neem*, and we won't have to use the trees at all. That is what we are all working towards.

□ *Has it been shown that neem has any deleterious effects on humans or is it conceivable that it might?*

Any plant substance or synthetic drug that has a beneficial effect always has some side effects. Otherwise, I firmly believe that it wouldn't even have the beneficial effect. Not a single medicine from among our thirty thousand can be said not to have some harmful effect, in a certain percentage of people., if used badly, or if used in excess, We already know *neem* has some irritating effect. It may affect some of the other fundamental mechanisms; we just don't know. This is why we have to do the toxicology with that part of the *neem* that we are going to use in our medicines. So, my answer to your question is: Yes, like any other drug it will have side-effects. In its use, a balanced view has to be taken of the benefits and side effects.

□ *Among activist groups, neem plant seems to have become emblematic of what is harmful about globalization. Why is it that neem plant has come to serve this purpose when many other plants have seen similar fates?*

Well, let's go back. Twenty-five years ago, no one was bothered about *neem* plants. I think *neem* is the first one to hit us and that makes such a massive impact. The impact is based on religion. *Neem* has always had a place in the Hindu religion as a plant that purifies; it has been used traditionally during various functions; it has been used locally for healing; and it has also been used as an insecticide. So, all of this together made us feel that this is our plant. *Neem* is indeed an indigenous plant. And then, suddenly, we found that a patent had been taken and we were very hurt about it. We are using it today as an emblem but I don't think there is anything special about *neem*. It was just the first plant to be sought to be patented. There are many other plants which will come the same way—I foresee *tulsi* (which is known as

Osylum sanctum) becoming a similar point of national honour.

If tomorrow, a firm from outside India patents a product from *tulsi* for anti-stress activity and protection against respiratory diseases, I think we will have the same feeling. Every household will feel outraged; every house has a *tulsi* plant and will say, "Look, we are using it, how come somebody outside this country has patented it." This is what I feel. First, it will come to *tulsi*, next it will come to *satawari*, then *ashwagandha*; these are all legendary plants of our heritage. If anyone takes them or works on them, we will feel extra protective and possessive even though we have ignored exploring their full potential, but, that is how we are likely to react.

But let us also look at the reverse scenario. *Taxis bakarta* was discovered in the USA. Now, we in India are working on it. And, we have taken leads from the West, that it is good for treating ovarian cancer. The original work was not done in India.

But later we found an Indian plant, whose leaves have the same substance. An Indian pharmaceutical firm is now going to put it in the market. Now, no one will tell us that you are exploiting *Taxis bakarta* which is a South American plant. It's free for all to do it. That is the world today. You can't have such technological advances on the one hand and hope that they will standstill whenever you want it to.

Our research institution has been coordinating some of the work being done on medicinal plants throughout India. Although clinical trials have not begun as of yet, *neem* is one of these medicinal plants. The main emphasis of the program is to define areas in traditional medicine that may suggest approaches to diabetes, hepatitis, bronchial asthma, and general healing. □

Dr. Roy Chaudhury is Chairman of the Scientific Advisory Group on Traditional Medicine, Indian Council of Medical Research.

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