

Measuring the Effects of the Ephedra Ban

***Acupuncture Today* Interviews Dr. Dan Wen**

By Editorial Staff

Few people know about the consequences of the Food and Drug Administration's recent ban on ephedra better than Dan Wen, the president of Honso USA, a well-known pharmaceutical company.

Since 2000, Honso has imported herbal formulas from Japan for distribution and sale throughout the United States. While Honso continues to distribute more than two dozen different herbal formulas to acupuncturists and other health care providers, the ephedra ban, which went into effect April 12, has forced the company to stop selling numerous products that contain ephedra altogether - a situation faced by hundreds of herbal suppliers and manufacturers across the country.

In this exclusive interview, *Acupuncture Today* speaks with Dr. Wen about the financial impact the ban has had on the herbal medicine industry, and the efforts Honso has made to communicate with the FDA on what constitutes "traditional Asian medicine." He also discusses ways the profession can unite, and forecasts what the Oriental medicine profession may look like if the FDA's power to regulate herbal products goes unchecked.

Acupuncture Today (AT): Good afternoon, Dr. Wen. How long has Honso been distributing herbs in the United States?

Dan Wen (DW): Honso is a daughter company of a Japanese manufacturing company. The parent company has been in existence in Japan since the 1930s. It became a pharmaceutical company in the 1970s. Here in the States, we started in 2000, in Phoenix, Arizona. We're in our fourth year now.

AT: How many different products do you sell?

DW: We have two lines of Chinese herbal classical formulations. One is our retail line, which is actually the type of product used in Japan as over-the-counter drugs. That line consists of 17 herbal formulations. Now, because of the *ma huang* issue, we're reducing it to around seven to 10 products. Two years ago, we started distributing professional herbal granule products, which are only accessible by licensed health care practitioners. This line consists of 35 formulations. Among them are five that contain ephedra, so we'll have to take them out now

All of the formulations are classical, mostly *Shang Han Lun*-types of herbal formulations. The professional-line products are standardized granule products that come in a unit-per-dose pack. The retail line is in tablet form.

AT: You mentioned *ma huang*. That's what we wanted to talk about primarily. If you could, describe what the typical process was for creating formulas and selling herbs before the ephedra ruling went into effect in the U.S.

DW: In the U.S., we're just a marketing and importing company; all of the products are manufactured in Japan. As you know, Chinese herbal products are highly regulated items in Japan. Our main line - the professional product line - is what's called an "ethical drug" in Japan. It is prescribed only by physicians and pharmacists, and is reimbursed through national health insurance. The manufacturing is under very strict scrutiny under the Ministry of Health, Labor and Welfare in Japan. All of the facilities are Good Manufacturing Practices (GMP) certified, and products are standardized to contain certain levels of constituents. We measure for two or three chemical markers from every batch and every lot we produce. All ephedra-containing products are standardized to contain certain levels of, among other things, ephedrine alkaloids.

When we imported the products into the States, there was no issue at all before the ephedra ban. We just brought them in, and the FDA would usually have an inspection, mostly on the labeling, to see if we were in compliance with regulations, namely DSHEA (the Dietary Supplement Health and Education Act). Then, we just distributed them to the profession in the U.S. We're adding Canada now, also.

AT: How have things changed since the ruling went into effect?

DW: We, like many other Chinese medicine manufacturers in the U.S., were very optimistic when we read the clause that contained the FDA final rule on the ephedra ban, which indicated clearly that traditional

Asian medicine would be excluded from the ban, and that if it was a traditional Asian medicine, we could still continue selling it. At that moment, at the beginning of this year, when the ban was still in discussion, we were very optimistic.

We asked ourselves two questions: 1. Is our line a traditional Asian medicine? The answer to that was yes, of course. 2. Is our line distributed to traditional Asian medicine practitioners? The answer was yes, again. So we thought, very optimistically, that our products could be distributed, that our ma huang or ephedra-containing products could be continued to be sold, even under the ban.

Like you, like us, like everybody else in the profession, we felt we were left "out of the loop." When the products were imported from Japan to the U.S., at the importing office in San Pedro - that's where the FDA has a branch office inspecting all the imported dietary supplements - all of the products that we imported were categorized as dietary supplements. The law says if it's a dietary supplement, then it's under the ephedra ban, under the final ruling. The problem at the FDA's end is that there is no such category to distinguish traditional Asian medicine from dietary supplements. Even the final rule says that "traditional Asian medicine" is excluded from the ephedra ban, but the FDA's importing operation at San Pedro does not have a tool to exclude these products.

The first shipment we had arrived here in January, 2004. Among many other items, there were two formulas the FDA examined. One contained ephedra; the other contained only pinellia (*ban xia*). One product was a coix formula (*yi yi ren tang*), the other was a major bupleurum formula (*da chai hu tang*). Those two formulas were detained. We had many communications with the FDA branch office in San Pedro. We sent e-mails, we sent letters, and we showed the FDA clearly that these were classical Chinese herbal formulations. We even sent copies of pages describing those formulations from Dan Bensky's book, *Chinese Herbal Medicine: Materia Medica*. We indicated clearly that our formulations were actually Chinese herbal medicines. And we showed the FDA our distributing methodology, in that we require the buyers to be licensed health care professionals. Even on our product labels, we had a sentence put on two years ago when we started distributing the products, which says: "This Honso Kampo formula is for licensed professional use only." We have that sentence on every box.

After all of these communications with the FDA, at the end of June, the final e-mail I received from them said, "No one is excluded from this regulation. Our detention stands." This was for the shipment we received in January containing those two herbal formulations.

AT: Have you gotten the formulas back yet?

DW: They were refused for entry. We were informed to either ship the refused products back to their origin or destroy them under FDA monitoring. We have chosen the latter option.

AT: The FDA destroyed them?

DW: Yes.

AT: How much did that end up costing you?

DW: It was a small shipment of items that we shipped with other things together. That was the first shipment that we had detained.

Our second shipment of ephedra-containing products is currently under detention. That shipment, which is a lot bigger, came in April, which was bad timing, as you can see. In that shipment, we had about 10 to 15 products altogether, but there were three items detained eventually. All three contained ephedra - a formula called Minor Blue Dragon formula, the coix formula again, and ephedra, apricot kernel, gypsum and licorice formula.

We have calculated out that from the total products detained from the two shipments, the wholesale value of those products to the professionals is over \$35,000. Those items in the second shipment are under detention now, and we're just waiting for the FDA to send us a notice that they're going to refuse them. (*Editor's note:* Since the publication of this article, *Acupuncture Today* has learned that Honso's second shipment was also officially refused by the FDA, and that Honso has been ordered to either destroy all ephedra-containing products in the shipment, or ship them back to Japan.)

AT: If you wanted to ship the formulas back, would you have to pay for that, as well?

DW: Definitely. Even destroying the items costs money.

AT: So your company not only loses money on the cost of the products and the arriving costs, you have to pay for the FDA to destroy the products?

DW: Yes. Exactly. We have paid the costs of destroying the first refused shipment. With the current shipment, it's a full pallet. It's just sitting in our warehouse, waiting for the FDA to take back and destroy.

AT: Do you know if this is happening to other herbal suppliers?

DW: What I've heard is that nobody is getting ephedra products through. I cannot speak for anybody else, just us. This is our situation. We are almost giving up on (selling) these items - these five items that contain ephedra.

On our Web site (www.honsousa.com), we have a list of those five ephedra-containing formulas. In every one of those products, Honso routinely measures ephedrine alkaloid content, and that specification is validated by the Ministry of Health and Welfare in Japan. Those amounts of ephedrine alkaloids per day are well below the safety levels the FDA announced a few years ago.

AT: And even with the testing, the FDA is still withholding your products.

DW: Definitely. It's a zero-tolerance policy. Ephedrine alkaloids are not allowed to be imported into the country as dietary supplement products.

Interestingly, we have other products that contain *ban xia*. We have now started measuring the products that contain *ban xia* for ephedrine alkaloid levels. One of the products that we sell is a minor bupleurum formula that contains *ban xia*. Honso's quality control department has measured the ephedrine alkaloid contents in several lots, and the standard HPLC measurement could not detect the compound, but even with this kind of self-regulation and standard of specification, it's not allowed to be used by the profession here in the States. We feel it's a very unfortunate situation, and we had this kind of specification even two or three years ago, before this happened. We're doing this all the time - every product, every lot that we import.

AT: How do you think all of this is going to impact the profession a year or two from now?

DW: It's very obvious. Ephedra, *ma huang*, is one of the effective ingredients that practitioners use to treat respiratory disorders, so we've automatically lost a tool, a major tool, against these diseases. Once we start losing, one by one, these types of useful tools, what kind of profession are we going to end up being? That's the concern I have here. We're probably going to go back to a state where we can only use needles someday.

AT: What steps do you think the profession needs to take now, to ensure that situations like this don't happen in the future, and that this rule could be overturned or modified to allow it to be used by acupuncturists?

DW: I think we were all too optimistic during the discussion period of the ban. We all believed that the FDA put up this clause for the Asian medicine practitioner in the final rule, and we let our guard down. Even now, our customers are calling us, ordering products that contain ephedra, and when they find out that we don't have it available, they're surprised. Practitioners still believe they all have the right to use ephedra products.

Therefore, the first and most important thing to do is to have a wake-up call for every practitioner and their patients that ephedra products are banned altogether. We're losing these products due to the FDA final ruling, even though the ruling contained some favorable language toward Asian medicine practitioners. In our company, since our product line is relatively small, we can cut out five products out of our product line, but what's going to happen next time?

The next step should be to call upon all practitioners to unite and stand up to work together, and to appeal to the FDA and other legislative bodies to revise and modify the final ruling. As a manufacturer, we've worked very closely with other industry members and associations to communicate with the FDA and initiate a "practitioner call to action" on the ephedra ban. Obviously, manufacturers alone have not been strong enough to prevent the ban from happening. Now, it's the turn of the practitioners to stand up and get this thing moving forward.

Ultimately, I hope legislation can be initiated to add a new category between drugs and foods, which should be designated as "traditional medicine," to reflect the uniqueness of the alternative medicine practice. Under this category, all therapeutic agents that are not approved as drugs but used as alternative and complementary medicines should be included. The one sure thing is that this will take a tremendous effort to achieve, and a broader spectrum of professionals working together.

On a final note, we received a survey recently. The Japan Ministry of Health and Welfare sent a survey to all of the pharmaceutical companies in Japan that export products into the U.S. Specifically, it asks about what kinds of problems we're facing now, what we think we should do better to cooperate with the FDA, and what we would recommend the FDA do to solve the problem. That's something going on in Japan, and we are planning to submit our concerns over the ephedra issue to the Ministry of Health. Hopefully, it will go through the pipeline there, and we can get some feedback to the U.S.

AT: Thank you.



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