The Fair Market Value (FMV) component of consulting arrangements is one of most difficult areas confronted by drug and device companies. “You can structure your arrangements so that you fall squarely within a safe harbor sometimes, but not very often,” warns Katherine Lauer, a partner with Latham & Watkins in San Diego. As a result, in almost any situation where companies find themselves defending arrangements in this context, FMV is going to be an issue, she says.

According to Lauer, while it is important to understand the FMV methodology, there are a number of factors that companies should keep in mind when engaging a consultant in addition to the FMV calculation itself. Timothy Renjilian, senior managing director of the Atlanta office of FTI Consulting, takes a similar view. He says that if pharmaceutical executives begin by focusing on the FMV calculation, they will be missing an important part of the argument and probably starting in the wrong place. How companies get to that point in the first place and how they show the intent of the organization play big roles in defining what the FMV is, he explains.

One of the challenges in this area, says Lauer, is that there are no “hard-and-fast” rules to follow when engaging consultants. “If you are lucky enough to have an arrangement with a consultant that can fit within a safe harbor, give yourself a gold star,” says Lauer, “because that almost never happens.” The problem when you have consultants, she says, is that in order to fit in the safe harbor you must have compensation in the aggregate set in advance. “It is very difficult to do that and at the same time meet fair market value,” she says.

In addition, to meet the safe harbor, companies must schedule the intervals when services are performed, which is almost impossible to do, says Lauer. “As a practical matter, we are almost never going to be in the safe harbor,” she says.

Lauer says that makes it necessary to look to a variety of other sources of guidance to minimize risk. That way, when companies are on the back end defending these arrangements they can point to what took place on the front end, she explains.

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Experts explain how to structure consulting agreements to minimize compliance risk

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Legitimate need for the service. The second item, says Lauer, is the legitimate need for the service. She says companies must consider how to establish that need, who should participate in that decision, and how it should be documented. “The second thing a prosecutor is going to ask is, ‘What is the service and why do you need the service?’” she says, “so you need to demonstrate legitimate need.”

Services are provided. Third, says Lauer, companies must make sure the services are provided. “Just having a written contract of something that you really need does not make a difference if you are
paying somebody for something that they didn’t do,” she explains. “That is going to be suspect.”

Compensation at FMV. Compensation at FMV is a key consideration, says Lauer. (Several techniques for establishing compensation will be examined in the next issue of Rx Compliance Report).

All of the preceding are documented prior to payment. To the extent possible, the preceding considerations should be documented prior to payment, says Lauer, because back-end documentation will always be viewed suspiciously by an enforcement agent.

The PhRMA Code—consultants
The PhRMA code also addresses consultants, notes Lauer. Similar to the OIG’s guidance, the PhRMA code points to written agreements that specify the services and compensation as well as legitimate need for the services.

Criteria for selection related to legitimate need, not business generation. One of the most important considerations, says Lauer, is separating sales and marketing from the selection of consultants in order to avoid the suggestion that those selected are the biggest customers as opposed to the most qualified.

While it is not often seen anymore, adds Renjilian, some companies used to make explicit return-on-investment calculations and specific quantification of business generated by individual physicians. That is clearly a mistake in this context, he says.

The PhRMA code also indicates that the number of consultants should be no greater than the work needed, that records should be maintained regarding the use of consultant work product, and that the venue and circumstances for the meeting is conducive to providing services, social or entertainment events, notes Lauer.

PhRMA code—speaker training
The PhRMA code also addresses speaker training, which is important to consider because there is an overlap between consultants and speakers, says Lauer. In short, she says, the PhRMA code indicates that participants can be compensated for their time along with reasonable expenses for travel, lodging, and meals if participants actually receive training on the company’s products in compliance with FDA regulations. It is also important that the training results in the provision of valuable services to the company, and that participants meet other criteria for consultants, she adds.

Advamed Code—consultants
Notably, says Lauer, the Advamed code addresses consultants in somewhat more detail than the PhRMA code. However, the themes are similar, she says. For example, the Advamed code says it is appropriate to pay for bona fide consulting services if there is FMV for the time and reasonable factors for travel, meals, and lodging.

According to the Advamed code, factors indicative of bona fide consulting arrangements include:

- Agreement must be in writing, signed, and specify services;
- Compensation consistent with fair market value;
- Legitimate purpose and need for services identified in advance;
- Selection based on consultant’s qualifications and expertise;
- Venue and circumstances of meeting:
  - Appropriate for information exchange;
  - Hospitality—modest, subordinate to meeting purpose, and;
- Written protocol for research services.

If pharma executives begin by thinking about the FMV calculation itself, they will be missing an important part of the argument and probably starting in the wrong place, warns FTI Consulting’s Timothy Renjilian.
Checklist for consulting agreements
According to Lauer, whether companies look to industry sources or government sources, it pays to structure arrangements on the front end, according to established policies and procedures that include checklists.

Here is an example of a checklist that can be used for consulting agreements:

• Does the company have a legitimate need for the consulting or other personal services?

• Is the company subsidizing part of the customer’s ordinary cost of doing business?

• Is the company deriving benefit from the services, or is it “makework”? 

• Does the company pay for needless repetition of services? Does the company have more consultants than it needs?

• Does the company pay fair market value for the services actually provided?

• Does the company require documentation of services provided prior to making payment?

• Is there a written agreement in place for all relationships?

Deriving benefit from the consultant agreement is a major consideration, says Lauer. “We see an awful lot of situations where agreements look fine on their face,” she says. “But when you look behind the work that is being done, you realize that this is not work the company really needs or really derives any value from.” Rather, she says, it is just a way to dress up an arrangement to get money to a doctor who is going to prescribe the drug.

That also comes up in connection with the needs assessment, says Rejilian. “It is not just do we need the service, but how much of this service do we need? How many speakers do we need to train? How many people gathering clinical data do we really need?”

The key, he says, is to make sure the totality of the program makes sense and not just the individual arrangements.

Checklist for clinical trials
According to Lauer, the questions companies face in the area of clinical trial agreements differ somewhat from some other types of consultant agreements.

“One of the things we see a lot are clinical trials that are initiated by the sales and marketing department as opposed to regulatory affairs or R&D,” she reports. Lauer says this refers not to the trial itself but the agreement for the trial and the suggestions for who should participate.

One of the questions that should be asked, she says, is who initiated the idea for this trial and who initiated the idea that this particular person should take part in this trial.

“We sometimes see clinical trials when there is really no scientific reason to have the trial,” says Lauer. It is called a clinical trial but it is really just a sham and a way for the physicians to get money, she says. These data are sometimes not needed for the business, she explains, and the spreadsheets and databases are sometimes no more than marketing tools.

Sometimes, the company actually does the work that the customer is asked to do, says Lauer. Likewise, sometimes equipment or personnel are provided to the consultant or to the physician “in order to gather data.” But the computer equipment, IT equipment, and sometimes even nursing personnel, end up in the physician’s office helping their practice under the guise of providing data for the clinical trial. “That is always a question you want to ask,” she warns.

Clinical trial publications are another consideration, says Lauer. Sometimes, we see the companies actually ghostwriting the clinical trial reports, which is a red flag the physician is paying for something he is not doing.”
Here are some of the pertinent questions that should be asked:

- Who initiated the idea for the trial—was it the physician or sales and marketing?
- Is the “clinical trial” or “research” calculated to generate meaningful, usable information?
- Will the company actually use the data?
- Did the customer or the company do the work? Is the company able to use the equipment or personnel that the company pays for in his/her practice?
- Did the company pay fair market value for the services? Is it appropriate to use the physician’s hourly rate for patient care services for research activities?
- Is the company ghostwriting the clinical trial publication? Is the investigator being paid for it?

**Checklist for royalty agreements**

Many physicians have lucrative royalty agreements, especially in the device industry. The real question, says Lauer, is whether they contributed meaningful intellectual property or just changed the color, packaging, or name of the device. In many situations, there is the suggestion that what was contributed is mostly a lot of business for the device manufacturer.

Here are several questions that should be posed:

- Has the physician or other customer contributed meaningful intellectual property?
- Is the royalty payment commercially reasonable and based upon the actual contribution to the value of the invention?
- Does the company have documentation from the physician to substantiate his contributions and work product?

**Key roles to consider**

According to Lauer, every company must determine for itself who is defining the need for consulting agreements. However, sales and marketing should never be on the committee that makes this decision, she recommends.

The same holds true for the selection of consultants, says Lauer. “You want this to be your R&D, medical affairs, and regulatory rather than marketing,” she says.

In terms of monitoring consultant activity, Lauer says, this is a great place for internal audit and compliance to get involved. Needless to say, it should never be sales and marketing, she says.

Approval of compensation should also be carried out by someone independent from sales and marketing such as the CFO or another senior executive. “You need to think about whom you want to have approve deviation,” Lauer explains, “because deviation is the first thing a prosecutor is going to look at.”

“That is an important process,” concurs Renjilian. Many corporate policies and deferred prosecution agreements include specific standards or thresholds above which compensation needs to go through some sort of internal approval process, he says. “It is helpful to have a standard that you are normally operating within,” he says. But it is also important to have a sound process for deviation from that standard so the proper people within the organization are looking at those exceptions to make sure they are appropriate, says Renjilian. The thought process behind those deviations should always be documented, he adds.

Here are several specific questions that should be considered:

- Who defines the need?
- Who selects the consultants?
- Who monitors consultant activity?
- Who approves compensation that deviates from previously established standards?

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**Renjilian says it is important to make sure the totality of the program makes sense and not just the individual arrangements.**

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