

BVR'S GUIDE TO HEALTHCARE VALUATION 2009 EDITION

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What It's Worth

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What It's Worth

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CHAPTER 22
FAIR MARKET VALUE:
ENSURING COMPLIANCE WITHIN THE
LIFE SCIENCES INDUSTRY

Fair Market Value: Ensuring Compliance within the Life Sciences Industry

By Ann S. Brandt, PhD, Jason Ruchaber, CFA, ASA, and Timothy R. Smith, CPA/ABV

OVERVIEW

The “life sciences industry,” as it is frequently termed, encompasses a broad range of very different market sectors, including pharmaceutical, medical device, medical supplies/ equipment and biotechnology industries. Issues facing these sectors are similar in terms of escalating costs, increasing pressure from shareholders and a stringent regulatory environment. While these may be the best of times in terms of technological advances, companies within the life sciences industry are experiencing the same regulatory “wake up call” that the hospital sector experienced years earlier.

This chapter deals with the determination of fair market value (FMV) within the life sciences industry. In an effort to control health care costs and to maintain a level playing field within the healthcare industry, federal regulators are increasingly focusing their efforts on prosecuting violators of the anti-kickback and Stark laws as well as the False Claims Act. Resulting judgments to date have not been trivial, nor have they been isolated to any one particular segment of the life sciences industry. Numerous medical device and pharmaceutical companies have been targeted by the government, and all indications are that such compliance actions will increase for those companies that fail to comply with these laws, whether intentionally or not.

The determination of the FMV of most types of relationships between physicians and healthcare entities that compensate them, including pharmaceutical and medical device companies (as well as hospitals, clinics and clinical research entities), appears to be a significant issue for the government. As a result of recent action by the federal government, many pharmaceutical companies and medical device companies have been required to execute corporate integrity agreements (CIA) as part of their settlements.¹ CIAs are intended to cause the offending organization to develop a plan of self-improvement and self-monitoring, coupled with independent outside review to insure that the risk of future violations is minimized.

One element of a number of CIAs that have been executed with the government is the requirement that independent third party fair market value analyses be performed for all physician compensation arrangements over a certain dollar value threshold. For example, in the recent case of five of the country’s largest medical device companies, this minimum threshold was identified to be compensation of \$500 per hour. These specific requirements imposed by certain CIAs signal the government’s concern when physicians receive “high” rates of compensation.

REGULATORY ISSUES IN THE LIFE SCIENCES SECTOR

Regulatory restrictions within the healthcare industry often prohibit marketing practices that are common in other less regulated industries. For example, the federal anti-kickback statute places significant constraint on the marketing and sales practices of healthcare-related companies. As a result, fraud and abuse enforcement activities tend to focus on areas the government believes offer the greatest potential for abusive arrangements, including arrangements between physicians and those entities that derive revenue from federal healthcare programs.

The Anti-Kickback Statutes

The federal anti-kickback statute places significant constraint on the marketing and sales practices of healthcare-related companies. This statute provides that *anyone who knowingly and willfully pays or receives anything of value to influence the referral of business, which is reimbursable in whole or in part by a federal healthcare program, can be charged with criminal penalties, civil monetary sanctions, and even exclusion from federal healthcare programs.*²

Clearly, relationships between medical device companies and physicians are encountering increased scrutiny from regulators. Questions are being raised with regard to the amount of money physician advisors and consultants are being paid, as well as possible conflicts of interest that may be inherent in these arrangements. The reality is that while relationships between physicians and medical device companies are not black and white, the relationships are often perfectly permissible provided they are appropriately structured.

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With regard to the services being provided, experienced physicians offer a level of expertise that often cannot be duplicated by any other group of professionals. As a result, their input into product design and development, as well as their insight into market requirements, is invaluable. In fact, arrangements between medical device companies and physicians encompass a whole host of necessary services including product design, development, research and clinical trials, physician training and marketing. The government's concern with these types of arrangements revolves around the idea that they could be used as a vehicle to induce purchasing or prescribing of the company's products. Therefore, the government is focusing its attention on various types of "*consulting fee*" arrangements³ to determine if they are tied to prescribing practices or to usage patterns involving the company's products. Of obvious importance in this scrutiny is whether the fees for these services appear to be in excess of FMV for actual services rendered. Similarly, medical device companies are being targeted for investigation when there is doubt as to the legitimate need for the particular consulting services, or when there is a lack of documentation of the services rendered.

By way of example, there have been several well-publicized enforcement actions for which the alleged illegal conduct included improper or sham consulting arrangements. In July, 2006, Medtronic reached a settlement agreement with the U.S. Department of Justice in which it agreed to pay \$40 million to the United States and participating states to settle allegations stemming from two *qui tam* lawsuits.⁴ These lawsuits, which were brought under the federal False Claims Act (FCA), allege that Medtronic made illegal payments to physicians to promote its spinal products in violation of the federal healthcare program anti kickback statute. The alleged illegal payments included (i) consulting and royalty agreements for which little or no work was performed, as well as (ii) all expenses paid trips to lavish venues. In addition to the \$40 million payment, Medtronic was required to enter into a five year CIA.

In another well-publicized case, to resolve allegations under the FCA, four major medical device manufacturers entered into civil settlement agreements with the government for a combined total of \$311 million. The government alleged that the companies provided financial incentives to physicians including consulting agreements and lavish trips to persuade physicians to use their joint replacement products. The government alleged that by offering illegal inducements, the identified companies violated the FCA by causing hospitals to seek and obtain reimbursement from Medicare. To avoid criminal prosecution, each of the identified companies entered into an 18-month deferred prosecution agreement, under which they agreed to multiple remedies including the posting on their web sites of the names of consultants, along with the amount of payments to these consultants. In addition, each of the identified companies entered into a five year CIA.

Another case involves a physician who accepted kickbacks from a medical device company in return for using the company's products. Even though criminal prosecutors have rarely directly targeted physicians, a physician who accepts a kickback in return for using a product can be as culpable as the company that provided the kickback. Dr. Patrick Chan, a neurologist in Arkansas, paid a \$1.5 million civil settlement in January, 2008, and pled guilty to soliciting and accepting kickbacks from Blackstone Medical. The kickbacks included gifts and payments for sham consulting agreements and fake research studies.

In another recent case, Lincare Holdings paid \$10 million and entered into a five year CIA for allegedly providing kick-back payments to physicians in the form of sporting and entertainment tickets, rounds of golf, golf equipment, fishing trips, meals, office expenses and medical equipment, all of which were intended to induce the physicians to refer patients to the company. The government also alleged that Lincare provided kickbacks in the form of purported consulting arrangements that had no basis or foundation for payment. In addition the government alleged that Lincare violated the Stark Law by accepting referrals from parties to the consulting agreements.

The Stark Law

The federal physician self-referral ban (commonly referred to as the "Stark" law) prohibits referrals by a physician, or an immediate family member⁵ to an entity for "designated health services"⁶ if the physician has a "financial relationship"⁷ with the entity receiving the referral. Within the framework of the Stark Law, (i) the physician may not make a referral to the entity for the furnishing of designated health services for which payment may be made under Medicare or Medicaid, and (ii) the entity may not bill for designated health services furnished pursuant to such referral. It is also important to note that the Stark Law is not an intent based statute; therefore, receipt of a referral from a physician where a financial relationship exists results in a violation of the law, regardless of intent. Because it is not necessary to prove intent, a physician who has a financial relationship with an entity cannot make a referral to

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the entity for the furnishing of designated health services, unless it is demonstrated that the arrangement qualified for one of the identified personal services exemptions (or the so called “safe harbors”).

In making the determination of whether the Stark statute applies to a particular arrangement, three questions must be answered. First, is the referral for a designated health service? Second, does this arrangement involve a referral of a Medicare or Medicaid patient by a physician or an immediate family member of a physician? Third, is there a financial relationship of any kind between the referring physician or family member and the entity to which the referral is being made? If the answer to any question is ‘no’, Stark does not apply. If the answers to all three questions are ‘yes’, then it is necessary to determine whether the arrangement falls within a statutory exception (*i.e.*, a safe harbor). Within Stark II Phase III regulations, which went into effect on December 5, 2007, CMS modifies and clarifies the Stark Law exceptions, particularly the regulations governing physician compensation arrangements. For the purposes of this chapter, we will discuss just one of these safe harbor changes ...the one that deals with FMV.

Within the framework of Stark II Phase II, CMS created a voluntarily safe harbor provision within the definition of fair market value applicable to hourly payments to physicians for their personal services. Specifically, CMS identified two acceptable methodologies for calculating the FMV of physician services. The first method limited the hourly payment to the average hourly rate for emergency room physician services in the relevant market, provided there were at least three hospitals with emergency room services in the market. The second method was based on the average of the “50th percentile national compensation level for physicians in the same specialty” using at least four of six specified salary surveys, and dividing the result by 2,000 hours to establish an acceptable hourly rate.

In response to a broad range of negative industry comments concerning these methodologies, CMS eliminated specific reference to these methodologies in Phase III. CMS, however, indicated that it would continue to scrutinize fair market value arrangements as an essential component of many Stark Law safe harbors. CMS also addressed concerns regarding overreliance on independent appraisals, explaining that “while good faith reliance on an independent valuation (such as an appraisal) may be relevant to a party’s intent, it does not establish the ultimate issue of the accuracy of the valuation figure itself.”⁸ CMS stated that “the appropriate method for determining fair market value for purposes of the physician self-referral law will depend on the nature of the transaction, its location, and other factors and that use of multiple, objective, independently published salary surveys remains a prudent practice for evaluating fair market value.” It is also important to note that the regulations generally allow “any commercially reasonable methodology” for calculating fair market value.

Some recent Stark cases include the following:

- On March 17, 2008, Hardeman County Memorial Hospital, a 24-bed critical access hospital in rural Quanah, Texas, reached a settlement agreement with the OIG and the Department of Justice regarding an alleged 11 year long violation of the Stark law. In conjunction with the settlement agreement, Hardeman County Memorial Hospital was ordered to pay \$398,231 and enter into a 3 year CIA.
- In May 2005, St. Joseph Mercy-Oakland Hospital in Pontiac, Michigan, paid a \$4 million settlement related to a number of potential Stark Law violations that the hospital self-disclosed to the OIG. The hospital was not required to execute a CIA.

A common misconception is that the Stark law is the same as the anti-kickback statute. They are different laws, in different titles of the Social Security Act and different in scope. While the Stark statute pertains only to physician referrals under Medicare and Medicaid, the anti-kickback statute is much broader and affects anyone engaging in business with a federal health care program. The Stark statute does not require bad intent; a tainted financial relationship violates the Stark law regardless of good intentions. In contrast, the anti-kickback statute requires specific intent and violations may result in criminal actions.

The False Claims Act

The FCA is the federal government’s primary civil remedy for improper or fraudulent claims. Originally enacted during the Civil War to reduce widespread fraud in government contracts, it applies to all federal programs, ranging from military procurement contracts to health care benefits. People who “knowingly” submit false claims may be found liable under the act for penalties of between \$5,000 and \$10,000 for each false claim plus up to three times

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the amount of the damages caused to the federal program. Specific intent to defraud the government is not required: the government need only establish that the claim submitted is false and that it was submitted knowingly, as defined in the statute. Therefore, the FCA covers activity that would not be included under the traditional definition of fraud, which requires actual knowledge and the intent to defraud. As with most other civil actions, the government must establish its case by presenting a preponderance of the evidence rather than by meeting the higher burden of proof that applies in criminal cases.

The FCA contains a *qui tam* provision that allows citizens, on behalf of the United States, to sue companies or individuals for false or fraudulent billings submitted to the government. While it applies to any false claim submitted to the United States government, the FCA has proven to be a one of the government's most potent weapons for combating Medicare and Medicaid billing fraud. The *qui tam* provision is a major reason for its success, because it encourages whistleblowers to expose fraud in return for a substantial percentage of money the government recovers. In general, a *qui tam* plaintiff can receive between 15% - 25% of the total amount recovered if the government prosecutes, and 25% - 30% if litigated by the *qui tam* plaintiff.

CMS reports that Medicare and Medicaid spending was over \$500 billion for the 2006 fiscal year. In CMS' 2006 *Management's Discussion and Analysis*, it recognized that one of the best ways to cut Medicare and Medicaid spending and maintain the integrity of the programs was to reduce Medicare and Medicaid fraud and abuse. For example, the Department of Health and Human Services reports that it collected almost \$2.3 billion in 2006 from false claims suits. By implementing and actively enforcing anti-fraud compliance laws, the government can recover more money and, thus, curb the amount of Medicare and Medicaid spending.

By way of example, since the FCA was revamped and strengthened in 1986, Department of Justice data indicates it has saved U.S. taxpayers more than \$20 billion.⁹ Estimates indicate that the federal government recovers \$15 for every \$1 invested in FCA health care investigations and prosecutions. In fact, the FCA is so effective that the 2005 Deficit Reduction Act included incentives for states to enact similar laws. Prior to this, state and federal government split any recovered funds on a 50/50 basis, but under the new law, states with qualifying false claims acts will get a 60/40 split of any recovered funds in their favor. This translates into approximately 20% more revenue from identified Medicaid fraud, not only by *qui tam* actions, but also by public agencies including the Attorney General's office and local District Attorneys.

Some recent FCA cases and their headlines include the following:

- **Walgreen's Pharmacy settles \$35 Million Qui tam case**—The Illinois based Walgreen's Pharmacy has agreed to settle a *qui tam* case for \$35 Million that involves drug switching of the following drugs: Ranitidine (or Zantac), which inhibits stomach acid production; Fluoxetine (or Prozac), an antidepressant; and Eldepryl, known generically as Selegiline, which is used with other medications to treat the symptoms of Parkinson's disease. Reports showed that Walgreens fraudulently increased reimbursement from Medicaid by switching the form of the drug dispensed to Medicaid patients while providing no additional medical benefit to patients.
- **Medtronic/ Kyphon Settle for \$75 Million**—Medtronic Spine, formerly known as Kyphon Inc., has agreed to pay \$75 million to settle a False Claims Act lawsuit which exposed the company's sales and pricing strategy which was designed to further fraud against Medicare. The case was filed by whistleblowers, who will receive \$14.9 million of the settlement as an award for helping uncover and prosecute the fraud on behalf of the American government and its taxpayers.
- **Biovail to Pay \$25 Million**—Biovail Corporation says it will pay \$25 million to settle criminal allegations related to kickbacks paid to doctors in order to induce them to prescribe Cardizem. The probe began after reports in *The Wall Street Journal* and *Barron's* revealed Biovail was paying doctors up to \$1,000 each to write prescriptions for Cardizem LA and write reports on the drug as a Phase IV clinical trial marketing scam.
- **HealthSouth Pays \$14.9 Million**—HealthSouth and two doctors have agreed to pay \$14.9 million (\$14.2 million to be paid by the company and \$700,000 to be paid by the two doctors) to settle charges the company was submitting false claims to Medicare and paying illegal kickbacks to referring physicians. The settlement results from disclosures made by HealthSouth in 2004 and 2005 to the U.S. Attorney for the Northern District of Alabama.

Industry Perspectives and Issues

The Pharmaceutical Industry

As regulators hone in on the relatively symbiotic relationship between pharmaceutical companies and the physicians who write prescriptions, it is inevitable that there will be heightened scrutiny of industry marketing practices. One outcome of this intensified focus is that regulators are increasingly concerned that payments to healthcare professionals could easily result in conflicts of interest by influencing judgment and prescribing practices.

Pharmaceutical companies are dependent on their marketing organizations to increase sales and expand market share, and these marketing organizations have succeeded in raising awareness of some very profitable pharmaceuticals. However, as successful as this type of marketing has been, the reality is that physicians are still the keepers of the prescription pad; therefore, a significant amount of marketing dollars continue to be focused on persuading physicians to write prescriptions for certain branded drugs.

Since it is clear that physicians need to understand the indications, actions and contraindications of medications they prescribe, physician education is of paramount importance. As new drug discoveries are made, no one questions the fact that physicians and other healthcare providers need to be educated about the unique properties and medical efficacy of these newer, potentially more effective (and often more costly) medications. However, busy physicians who may treat increasing numbers of patients, due to decreases in reimbursement, may have little time to meet with pharmaceutical representatives who are often forced to compete with patients for the physician's limited time.

In an effort to inform physicians about newly developed medications, it is becoming increasingly common practice for pharmaceutical companies to engage the services of "physician leaders" who serve as advisors and consultants to other physicians practicing medicine in their targeted markets. Experience has shown that physicians are more willing to listen to and change their prescribing patterns after obtaining information regarding the therapeutic effectiveness of new medications from other well-credentialed physicians. As a result, pharmaceutical companies engage legions of physician consultants and advisors to conduct promotional meetings and advocate on behalf of their products. Payments to these physician advisors and consultants, which often total millions of dollars per year, have become routine marketing expenses for pharmaceutical companies.

The Medical Device Industry

The competitive medical device market is characterized by rapid technological advances, frequent new product introductions, evolving standards, growing demand and increased scrutiny. Therefore, as costs associated with developing and successfully bringing new medical devices to the marketplace continue to increase, medical device companies are also dependent upon their marketing organizations to expand market share, while simultaneously limiting many historically successful marketing practices. For example, providing certain "perks" to physicians who use or recommend a particular brand of knee or hip replacement, by paying for first class travel to conferences for physicians and their families may have a significant impact on which implants the physician uses. Clearly, physicians play a critical role in deciding or strongly influencing which medical devices are implanted or otherwise used in a hospital procedure or inpatient stay for which the hospital is reimbursed. As a result, medical device manufacturers have a vested interest in persuading physicians to use or recommend a particular device.

As government regulators hone in on the symbiotic relationship between medical device companies and the physicians who use or recommend these products, it is inevitable that industry marketing practices focusing on promoting the sale of newer and more costly devices will be subject to increasing regulatory scrutiny. One outcome of this intensified focus is that regulators, who are increasingly concerned that any type of payment to a healthcare professional could potentially result in a conflict of interest by influencing medical judgment and clinical practices, are investigating a broad spectrum of arrangements.

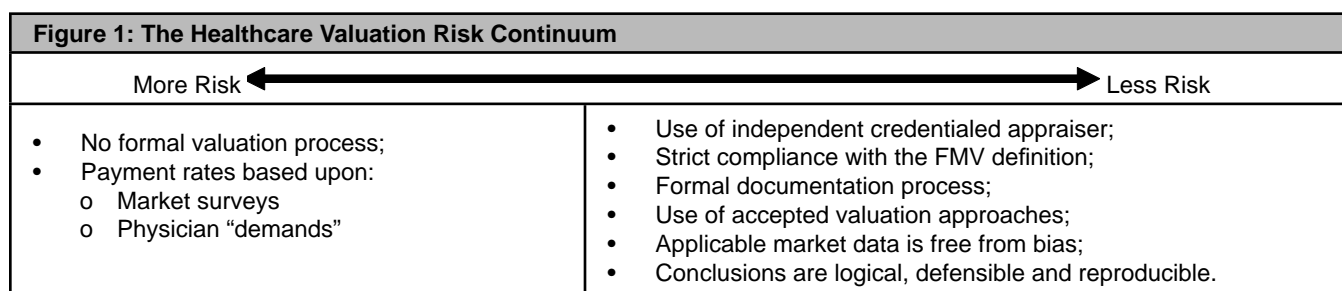
Fraud and abuse enforcement activities tend to focus on areas the government believes offer the potential for abusive arrangements, including arrangements between physicians and those entities that derive revenue from federal healthcare programs. As a result, relationships between medical device companies and physicians are encountering the results of increased scrutiny from regulators. In particular, a series of recent settlements between the government and medical device manufacturers, regarding payments to physician consultants, has triggered intensified efforts to ensure that physician relationships are fully compliant with the applicable laws.

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Despite these intensified efforts, the reality is that medical device companies need physician input to ensure that their products are designed, implanted and used appropriately. Experienced physicians offer a level of expertise that often cannot be duplicated by any other group of professionals. As a result, their input into product design and development, as well as their insight into issues involving surgical implantation of the devices, is invaluable. In fact, arrangements between medical device companies and physicians encompass a whole host of necessary services including (i) product design, (ii) development, (iii) research and clinical trials, (iv) physician training and (v) marketing. Therefore, as with the pharmaceutical industry, the government has focused its attention on various types of consulting fee arrangements to determine if they are tied to prescribing practices or to use of the company's products. Similarly, medical device companies are being targeted for investigation when there is doubt as to the legitimate need for the particular consulting services, or when there is a lack of documentation of services rendered.

MITIGATING RISK

Risk is not binary; rather it consists of an infinite number of points on a continuum ranging from *less* risk to *more* risk. Therefore, it is important to recognize that there is likely some degree of risk associated with every decision, although in some instances, especially those involving an area of increasing regulatory scrutiny, the risk level may be substantially greater. Figure 1 below provides a graphical depiction of the varying levels of risk:



As clearly described earlier in our chapter, relationships between life sciences companies and physicians are encountering increased scrutiny from regulators. Since it is routine for life sciences companies to engage physicians for the performance of multiple services, it is imperative to note that even if only one aspect of the remuneration for these services is to induce referrals, the anti-kickback statute is considered to be violated for the entire arrangement.¹⁰ Therefore, key questions focus on determining *the best way to mitigate the apparent risk in relationships between life sciences companies and physicians*. Therefore, given the broad scope of the anti-kickback statute, the “personal services” safe harbor may provide an appropriate framework for structuring the arrangement.¹¹ The personal services safe harbor provides protection for arrangements with physicians as long as seven standards are met:

1. The agreement is set out in writing and signed by the parties;
2. The agreement identifies all the services to be provided by the physician as well as the term of the agreement;
3. If the agreement is intended to provide physician services on a sporadic or part-time basis, the agreement specifies the exact schedule of any intervals, their precise length and the exact charge for such intervals;
4. The term of the agreement is for not less than one year;
5. *The aggregate compensation paid to the physician over the term of the agreement is set in advance, is consistent with fair market value, and represents an arms-length transaction that is not determined in a manner that takes into consideration the volume or value of any referrals;*
6. The services performed under the agreement do not involve any activity that violates state or federal law; and
7. *The aggregate services contracted for under the agreement do not exceed those which are reasonably necessary to accomplish the commercially reasonable business purpose of the services.*

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Of particular focus in the balance of this chapter are the requirements related to FMV and commercial reasonableness emphasized in italics above. Arguably, one of the most significant aspects of achieving the requirements of the personal services safe harbor involves establishing the FMV compensation associated with these arrangements. Fortunately, regulators agree that by basing compensation for legitimate services on a supportable FMV rate (assuming that the other requirements listed above generally have been met), the risk of payments being characterized as “in exchange for referrals” will largely be eliminated (*i.e.*, less risk as depicted above). However, defining FMV and developing methodologies to accurately determine FMV have proven to be a bit more elusive, as the government has historically provided little guidance on how FMV compensation should be calculated.

Valuing Thought Leader Compensation

Within the hospital sector, physicians who are compensated for administrative services are frequently referred to as medical directors. Within the life sciences sector, physicians who provide marketing/administrative services are frequently referred to as “thought leaders.” In this chapter section, key aspects of establishing the FMV of thought leaders are discussed.

The term “fair market value” is generally defined in the Stark regulations as the value in arm’s-length transactions, consistent with the general market value. In the context of consulting or advisory arrangements between medical device companies and physicians, “general market value” means the compensation that would be determined as the result of *bona fide* bargaining between well informed parties to the agreement who are not otherwise in a position to generate business for the other party.¹²

Determining the FMV of compensation paid by a life sciences company to a physician for advisory and/or consulting services is critical, but as indicated above, is not easily established. In particular, the volume or value of referrals cannot be considered in the determination (whether directly or indirectly), and market data cannot be considered to the extent that the data represents transactions between parties who are “in a position” to refer patients to one another. Therefore, compensation arrangements based on similar relationships should not be used as the sole determinant of FMV, as these arrangements may represent *tainted* values. This ultimately limits the techniques and data that healthcare valuers can use, and it makes FMV very difficult for life sciences companies and physicians to determine or even understand. Moreover, the consequences associated with failure to accurately determine the FMV of physician advisor and consultant compensation can be catastrophic to all of the involved parties.

The previously described series of government settlements with medical device and pharmaceutical manufacturers concerning payments to physician consultants provides some insight into the scope of the problem and likely solutions. While the settlements are not applicable to other companies and their physician consultant arrangements, they provide some helpful direction with respect to identifying potentially risky transactions. The settlement agreements reiterated that compensation for such arrangements must be within FMV, and further, certain settlements require the manufacturers to seek *independent third party opinions* to establish FMV for any physician consultant compensation in excess of \$500 per hour.¹³ In an interesting and perhaps confusing contrast, Hospital Corporation of America’s (HCA) corporate integrity agreement from December 2000 required that HCA obtain an independent third party opinion for any physician consultant compensation in excess of \$150 per hour.

Further confounding this analysis is that there is little valuation theory for an appraiser to rely upon in assessing these rather unique arrangements. The determination of the FMV of advisory and/or consulting relationships between physicians and medical device companies entails a significant amount of judgment. Unlike clinical compensation data for physicians, very little survey information exists related directly to these types of compensation arrangements, which, in many instances may significantly exceed the “proverbial” 90th percentile values provided by benchmark physician compensation surveys. Further, advisory and consulting arrangements can be quite diverse, making comparisons among arrangements difficult. Finally, a potential pitfall in looking to existing advisory and consulting arrangements as a basis for establishing FMV is that these relationships may be “tainted,” as they may contain an overcompensation bias (*i.e.*, pharma and medical device companies and physicians may, willfully or otherwise, establish arrangements that tend towards providing compensation for business referrals).

One aspect of FMV guidance from the federal government was provided in the Stark Phase III regulations issued by CMS in September 2007. In response to comments it received, CMS stated in Phase III that an FMV hourly rate “may be used to compensate physicians for both administrative and clinical work, provided that the rate paid

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for clinical work is fair market value for the clinical work performed and the rate paid for administrative work is fair market value for the administrative work performed” (72 F.R. 51016). CMS then further explained, “We note that the fair market value of administrative services may differ from the fair market value of clinical services [Emphasis added]” (72 F.R. 51016). This commentary tends to suggest that a healthcare valuator may want to “dig deeper” than the commonly used “opportunity cost” approach that is the result of converting physician compensation survey data from Medical Group Management Association (MGMA) and other sources into hourly rates. In fact, within the life sciences sector, we note that hourly rates for a particular physician specialty may range from \$150 per hour to \$1,000 or more per hour.

Therefore, a reliable and comprehensive valuation approach should provide (i) an evaluation methodology that analyzes each parameter in an objective, consistent and repeatable way; (ii) an FMV outcome that encompasses all relevant parameters; and (iii) an FMV outcome that can be supported via *independent* market data. Such an approach to determine the FMV range for physician consulting / development arrangements can be based upon consideration of certain parameters, including: the extent of the services (*i.e.*, the time requirement); the nature of the specialty; the credentials/qualifications of the advisor/consultant/presenter (*i.e.*, thought leader) and the specific services contemplated by the arrangement.

One available valuation approach entails the use of national and regional physician compensation survey data. Using the valuator’s judgment, this compensation data, considered across multiple years and adjusted to reflect payroll-related taxes and benefits, can be adjusted based on (i) the extent of thought leader time required; (ii) the specific requirements of the position; and (iii) the skills/experience of the specifically identified physician thought leader, in terms of acknowledged leadership in his/her specialty.

More specifically, in valuing a potential advisory arrangement between a life sciences company and a physician, consideration can be given to the following factors based on the specific duties and responsibilities of the advisory position:

- Number of hours associated with each duty and/or responsibility.
- The specific duties and responsibilities of the position.
- The complexity of each duty and/or responsibility.
- Level of leadership required.
- Specific objectives and deliverables.
- Potential impact of Thought Leader on organizational and/or product success.

In addition, the following factors related to the physician’s qualifications can be considered:

- Educational credentials and specialized training.
- Professional certifications.
- Leadership experience.
- Academic appointments.
- Research experience and funding history.
- Invited presentations.
- Publication history.
- Other professional leadership activities / reputation in the healthcare community.

Each of these factors should be considered and weighted, also giving consideration to any interdependencies among the factors (*e.g.*, if the requirements of the services are rather basic, it may be unnecessary to engage a particularly well qualified physician). Provided that these factors are evaluated in a logical and consistent manner,

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an objective valuation model can be developed to establish the FMV of physician consulting agreements applicable to the life sciences industry.

In addition to the approach described above, a *direct market approach* can be utilized, provided that the reference market data is free from potential referral bias. The surest ways of identifying reliable market data are to consider physician compensation arrangements in settings which are known to be free of referral bias (e.g., a medical director for a managed care organization) or to “cross walk” the arrangement to non-healthcare settings (e.g., rates paid to comparably qualified professionals providing comparable services in other industries). Physicians tend to be among the nation’s most highly educated and experienced professionals, and the duties and activities that they are involved in have considerable financial (and non-financial) implications. When considering the FMV associated with a particular physician thought leader performing a known set of services, there are many possible market “benchmarks” that can be considered. Depending upon the circumstances, these benchmarks may involve, for example, comparably qualified consultants and specialists in various industries as well as attorneys and any other professionals which seem to have value in comparability. However, in considering such market data, it is important to distinguish between the value attributable to the professional, as opposed to the value that may be attributable to the combination of the professional and the professional’s organization.

Valuing Clinical Trials Arrangements

In addition to consulting / development arrangements with physicians, life sciences companies frequently enter into compensated arrangements with physicians involving clinical trials or research studies. Clinical trials (or “studies”) are treatment protocols that are coordinated by pharmaceutical companies, biotechnology companies or medical device manufacturers (commonly referred to as “sponsors”) in order to obtain clinical data involving the use of its drugs or devices in the course of actual patient treatments. Clinical trials are classified as Phase I, II, III or IV. Briefly, Phase I and II trials are early stage studies that are intended to establish the safety and the apparent efficacy of a new drug or device which is not yet FDA-approved. Phase III clinical trials involve much larger groups of human subjects, and the results of Phase III testing are used by sponsors in support of their applications for FDA approval. Phase IV studies entail additional research that is conducted on a post-FDA approval basis. Sometimes referred to as “market studies,” Phase IV trials are intended to establish additional information concerning a drug which may, for example, lead to new indications or improvements in dosing guidelines.

Phase I and II clinical trials generally do not implicate healthcare regulations related to the FMV of compensation since the studies tend to be performed in a strictly research setting. On the other hand, Phase III and Phase IV trials oftentimes involve compensation agreements by and among the sponsors, physicians and other third parties such as hospitals or ambulatory treatment facilities. As these types of trials involve compensation payable to parties who are in a position to refer to one another, compliance with the FMV standard is required to demonstrate compliance with applicable federal and state healthcare regulations.

The clinical trials process is complex, and each trial requires the designation of a physician who serves as the principal investigator (PI) of the trial. There are a number of compensable arrangements inherent in clinical trials that must be consistent with FMV. First, the overall financial arrangement between the sponsor and the PI must be consistent with FMV. Typically, fees paid by a sponsor to a PI are based upon a study budget and include a fixed payment and variable payment based upon the number of patients. The fixed payment includes compensation for overall initiation of the study, as well as costs that may be assessed by third parties. For example, clinical studies involving hospital care must generally be approved by the hospital’s governing body called the institutional review board, or the “IRB.” The *per patient* fees can range from \$1,000 per patient or less to \$25,000 or more per patient. From the *per patient* fees, the PI may be responsible for purchasing certain services from third parties such as diagnostic imaging studies from a hospital or an imaging center. In some cases, the study budget may also contemplate payment to a study participant (*i.e.*, a patient).

When considering the FMV of a study budget between a sponsor and a PI, a valuator may want to give consideration to the PI’s overall duties and responsibilities, including (i) the intellectual process of identifying desired clinical trials in which to participate; (ii) the investment in one or more research nurses and required research infrastructure; (iii) the assumption of the overall responsibility and liability for the conduct of such trials. As such, the conduct of clinical trials (and the profits related thereto) is more akin to an ancillary service as opposed to a physician’s personally performed services. For example, a physician practice may offer in-house x-ray capabilities as a service

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to its patients, and the profits that the physician-owners may realize from such services generally do not bear any relationship to the physician's personal professional services.

As described above, many clinical studies reflect financial arrangements negotiated between sponsors and PIs. In other instances, organizations such as hospitals may be the party that attracts and negotiates the financial arrangement with the sponsor. Since a PI is still required for the study, a hospital may engage and compensate a physician to serve as the PI. Under this type of arrangement, the PI's services and involvement are significantly different than if the PI assumed the full risk for the study. Accordingly, the valuation methodology used in this case should focus more on the value of the physician's personally performed services.

A final valuation implication of clinical trials is that all trials are unique in both clinical structure and economics. Further, an active PI or a research-oriented hospital may be involved in dozens of trials each year. While it is critical to structure compensation arrangements that are consistent with FMV, it may be impractical from a cost and timing standpoint to value the individual payment streams associated with each and every clinical trial. Therefore, valuers and their clients may desire to develop compensation methodologies or guidelines that can be applied to a wide array of clinical trial arrangements as an approach similar to calculations of value.

Valuing Data Sets

Pharmaceutical companies, medical device manufacturers and other research entities require patient data in order to perform the clinical studies necessary to develop and successfully move potential drugs through the FDA's multi-phase approval process. Typically, researchers are not themselves providers of healthcare services, and accordingly, do not have the ability to capture the required data directly. Instead, they must commission clinical studies, either directly with providers or indirectly through outside researchers, universities, or clinical research organizations. However, regardless of which entity performs the actual research, the requirement for accurate and detailed patient data is essential.

Therefore, in addition to requiring the services of physicians, life sciences companies often need to acquire clinical data, outside of the clinical trial process, from direct service providers (e.g., cancer clinics or dialysis centers). When determining the fair market value of a data purchase, the purchaser should have a legitimate need for the data and, within reasonable economic parameters, would seek to obtain the data by alternate means in the event that the data was not available from an initially identified source. It is also important to assume that the life sciences company reasonably expects that the expenditure for the data set will result in a future revenue stream or research/teaching benefit that will support the expenditure from a stand-alone economic perspective. Therefore, the purchaser should not contemplate deriving value from any reciprocal action of the seller.

In terms of approaches used to determine the fair market value of data acquisition, the use of an income approach is generally not appropriate as a valuation methodology for several reasons, including (i) if utilized within the framework of a clinical research project, no direct measurable income stream will be derived from the transaction; and (ii) the data most likely represents a by-product of patient services and not a revenue generating mechanism in and of itself. In other words, the clinical entity is not directly in the business of generating profits from its data, and no records reasonably exist to allow for an assessment of the results of operations from data licensure transactions. Further, applicable healthcare laws and regulations may prohibit the consideration of the value of possible referrals among the parties.

In addition, the utilization of a cost approach is generally impractical and/or impossible for either the seller or the purchaser, since it is almost impossible to replicate the broad scope of the elements captured by the clinical entity due to the "by-product" nature of the data. Under a market approach, an appraiser may be able to locate industry experts who can provide information related to similar transactions involving data sales and/or licensures since such transactions are generally not available in any databases or in the public domain.

Valuing Intellectual Property Within the Life Sciences Industry

The pharmaceutical industry was one of the first industries in the United States to routinely use licensing programs as a means for identifying and commercializing new drugs. Prior to the rapid advances made over the last 30 to 40 years in computing and the development of sophisticated methods for mapping chemical paths, the process of finding and developing new drugs was arduous and exceptionally expensive, and the probability of successfully

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commercializing new pharmaceutical applications was extremely low. To combat these hurdles, pharmaceutical companies began licensing the right to screen the chemical libraries of industrial companies for pharmacological properties. This proved to be highly effective in reducing the cost of upfront research and development, and allowed existing discoveries to be further exploited through commercialization in previously unconsidered applications.

Today, intellectual capital has become a central focus of business strategy across all industries, and licensing activity for patents alone is estimated to account for more than \$100 billion in revenue for U.S. firms. The healthcare industry continues to play a key role in this market, and an understanding of the basic tenets of licensing is critical to understanding value in the life sciences.

Definition of Licensing

Licensing is the act of granting another person or entity the right to make use of a particular asset in a specific context or application, for a specific length of time, and within a specific geographical area. A license does not typically carry the full rights of ownership, and therefore license agreements must be defined narrowly to prevent conflicts of interest between the owner of the asset (licensor) and the user of the asset (the licensee). This is particularly important when the licensor is exploiting the asset in other commercial uses such as in the licensor's own product(s) or through additional licenses.

Why do owners of property find it advantageous to enter licensing arrangements? The basic conceptual framework of the license is to create a symbiotic relationship whereby both the owner of the property and the licensee share in the commercial success of the end product. An example of this type of situation might include an inventor who does not have the resources to successfully commercialize the invention, or an owner of property who does not have the necessary expertise to commercialize the product in a new area.

Asset Types

A licensing arrangement can be entered into for virtually any type of asset, but licensing activity generally centers on intellectual property such as patents, trademarks, copyrights, and technologies.

Patents

The United States Patent & Trademark Office (USPTO) is the governing body that issues patents and trademarks in the United States. The USPTO defines a patent as “the right to exclude others from making, using, offering for sale, or selling” the invention in the United States or “importing” the invention into the United States. Patent grants have a finite life typically defined as 20 years from the original date of the patent application. There are three distinct types of patents:

- 1) *Utility Patents* – granted for “the invention or discovery of a new and useful process, machine, article of manufacture, or composition of matter, or any new and useful improvement thereof.”
- 2) *Design Patents* – granted for the invention of a “new, original, and ornamental design for an article of manufacture.”
- 3) *Plant Patents* – granted “to anyone who invents or discovers and asexually reproduces any distinct and new variety of plant.”

Within the life sciences industry, most patents fall under the category of utility patents, and include chemical compounds, medical devices, and medical equipment.

Trademarks

Trademarks, or servicemarks, were established by the Lanham Act, and are described by the USPTO as “a word, name, symbol, or device that is used in trade with goods to indicate the source of the goods and to distinguish them from the goods of others. A servicemark is the same as a trademark except that it identifies and distinguishes the source of a service rather than a product.” Trademarks need not be registered to enjoy protection under the Act, however, most commercially used trademarks are registered with the USPTO. Trademarks registered after November 1989 are valid for a period of 10 years, and may be renewed for successive 10 year periods. Nearly every

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branded product with name recognition enjoys protection under the Lanham Act, but the most commonly observed trademarks in the life sciences are name brand pharmaceuticals and medical devices.

Copyrights

A copyright is a form of protection for original works of authorship (literary, artistic, musical, etc) established by the Copyright Act of 1976. A copyright generally establishes the exclusive right to print, publish, reproduce, perform in public, and/or create derivative works of the material. In the United States, copyrights are issued and registered with Copyright Office of the Library of Congress and have a term equal to the lifetime of the author plus 50 years. In some instances the copyright may be valid for a period of 75 years from the date of first publication. Within the life sciences copyrights may include medical texts, manuals, research papers, articles, diagrams, photos and the like.

Royalties

Compensation under a licensing agreement typically includes the payment of a royalty by the licensee to the owner/licensor for the use of the property. Royalties can take many forms, but are most frequently set as an upfront lump-sum, an annual fee, a percentage of revenue on products sold, a dollar amount per unit sold, or a combination thereof. Royalties paid on ongoing revenue or units of sales are referred to as running royalties. It is also common to see royalty arrangements whereby an annual minimum and/or annual maximum fee applies, the royalty rate decreases with volumes in a stair-step pattern, or royalties decline over time. These types of arrangements are appealing to licensees because they attempt to match the economic life of the licensed asset with the commercial success of the end product.

Royalty rates vary significantly from one licensing arrangement to the next, and there are many factors that must be considered when attempting to establish a reasonable royalty rate within the context of a specific licensing agreement. Frequently there is no single right answer, and royalty rates for seemingly similar technologies may vary widely. In the landmark case *Georgia Pacific Corporation v. United States Plywood Corp.*¹⁴, the court set out 15 factors that parties to a hypothetical negotiation would likely consider in determining a reasonable royalty. Though the case dealt specifically with reasonable royalties within the context of patent infringement damages, the context the court used was a hypothetical royalty arrangement that would have been negotiated had the parties negotiated immediately prior to the infringement. This is very similar to the hypothetical negotiation contemplated in the definition of fair market value¹⁵, and the factors the court used are applicable in assessing reasonable royalties for licenses outside the construct of patent infringement.

The 15 factors identified by the court are listed (in generic form to remove the patent infringement context) and briefly discussed below:

- 1) The royalty rates received by the owner of the property in other licensing arrangements for the same property, proving or tending to prove an established royalty.
Existing licensing arrangements for the subject property would tend to establish a reasonable royalty rate. However, it is important to consider relevance of prior licenses within the context of the contemplated license. Differences in the terms of the license (*such as factor #3 below*), the remaining life of the property (*such as factor #7 below*), and other factors presented in this list may limit the relevance of prior agreements.
- 2) The royalty rates paid by the licensee for the use of other property rights comparable to the property (for which a license is being contemplated).
Established rates paid by the licensee for similar properties in agreements with comparable terms may serve to establish the reasonable royalty rate. As with #1 above, however, terms of the license agreements should be carefully examined for comparability to the contemplated arrangement.
- 3) The nature and scope of the license, as exclusive or non-exclusive; or as restricted or non-restricted in terms of territory or with respect to whom the manufactured product may be sold.
Exclusivity – A license granting an exclusive right to use a property would generally demand a higher royalty rate than one which is non-exclusive (i.e. allows additional licenses to be granted)

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Geography – The geographical limitations of the license grant will influence the appropriate royalty rate. A worldwide license would typically demand a higher royalty rate than a license limiting use to a specific territory or boundary.

Use – The use of the license may influence the royalty rate. A license granting unrestricted use of a property would generally demand a much higher royalty rate than one which is defined narrowly, for example, a chemical compound to be used only in drug-coated stents.

- 4) The licensor's established policy on licensing, either by not licensing to others the use of the property to maintain a monopoly, or by granting licenses under special conditions.

An owner who is highly protective of their property rights, or who has an established policy of not licensing its properties, may justify a higher royalty rate. Such a rate would be necessary to induce the owner to deviate from their established policy. This is especially pertinent in infringement cases, but may be less so in the normal course of establishing a reasonable royalty rate between two willing parties. The absence of a history of licensing or policy restricting licensing should not be used as justification for a higher royalty rate in and of itself.
- 5) The commercial relationship between the licensor and licensee, such as, whether they are competitors in the same territory in the same line of business; or whether they are inventor and promoter.

License agreements between competitors tend to justify higher royalty rates than those of non-competitors. Even when the license is structured to limit the use of the product or if the product's application is in a market where there is no competitive threat, licensors are reluctant to allow competitors to gain information or profits that would advance their competitive position.
- 6) The effect of selling the licensed property in promoting sales of other products of the licensee; the existing value of the invention to the licensor as a generator of sales of his non-patented items; and the extent of such derivative (or convoyed) sales.

Licenses that allow the licensee to gain sales in other non-licensed products tend to justify higher royalty rates. For example, Bausch and Lomb may pay a higher royalty for new contact lens technology if they believe sales of the licensed product will lead to gains in sales of related products such as saline solution, etc. Higher royalty rates may also be justified if the license agreement allows the licensee to gain access to new commercial channels, new customers, appeal to a new population demographic, or augment their current commercial presence.
- 7) The economic or functional life of the property (i.e. expiration date of a patent) and the term of the license.

A product nearing the end of its life cycle will generally demand a lower royalty rate due to economic obsolescence, increased competition, and design around considerations. This may also be true for new technologies that are expected to have a short useful life.

In some instances, the license is written as a perpetual license. This might be seen in the context of a trademark license agreement where the name brand is expected to continue indefinitely. In these situations additional analysis may be required to evaluate the life of the economic benefit associated with the licensed property.
- 8) The established profitability of the property or products embodying the property; its commercial success; and its current popularity.

It follows logic that royalty rates for highly popular and/or highly profitable products are also high. As the popularity and profitability of the product diminishes so does the appropriate royalty rate.
- 9) The utility and advantages of the subject property over the old modes or devices, if any, that had been used previously for achieving similar results.

Products that have significant advantages over currently existing technologies justify higher royalty rates. This is due to the simple fact that products with significant utility advantages also enjoy significant profit advantages.
- 10) The nature of the subject property; the character of the commercial embodiment of it as owned and produced by the licensor; and the benefits to others who have used the invention.

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- 11) The extent to which the infringer has made use of the subject property; and any evidence probative of the value of that use. (*outside the context of infringement, the intended use of the subject property may be a substitute*)
- 12) The portion of the profit or of the selling price that may be customary in the particular business or in comparable businesses to allow for the use of the subject property or comparable properties.

A common rule of thumb, referred to as the Goldscheider rule¹⁶, suggests that a reasonable royalty represents 25% of the pre-profit expected to be made through the use of the licensed asset. There are also many databases that can be used to search for comparable license transactions within a given industry. In some cases, these databases can provide insight into the royalty rates being paid for similar properties. However, these should be referenced cautiously, as a truly comparable license transaction may be difficult to identify, and over-generalization may miss many of the nuances of the particular license arrangement.
- 13) The portion of the realizable profit that should be credited to the invention as distinguished from other elements of the end product, such as the manufacturing process, business risks, or significant features or improvements added by the infringer.

Understanding the relative contribution of the licensed property to the overall utility of the end product may be helpful to the determination of a reasonable royalty. A license arrangement whereby both parties contribute technologies that equally support the end product may justify a profit split of 50/50. An example of this might be a owner of a medical laser device licensing sophisticated positioning and tracking software to control the movement of the laser.
- 14) The opinion of qualified experts.

Frequently professionals in the licensing industry will have experience and expertise which can be helpful in establishing the reasonable royalty.
- 15) The amount that a licensor and a licensee would have agreed upon if both had been reasonably and voluntarily trying to reach an agreement; that is, the amount which a prudent licensee—who desired, as a business proposition, to obtain a license to manufacture and sell a particular article embodying the subject property—would have been willing to pay as a royalty and still be able to make a reasonable profit and which amount would have been acceptable by a prudent patentee who was willing to grant a license.

Though this list is fairly comprehensive, there are additional factors that should be considered in determining a reasonable royalty rate. These may include cost to design around the subject property (recreating the asset vs. licensing) and availability and preponderance of non-protected alternatives. It stands to reason that a licensee would not reasonably pay a royalty rate in excess of the cost to design or develop their own property with the same functionality (assuming it was possible to do so). Royalty rates will also be limited by the availability of acceptable alternatives. A licensee may prefer to have the subject property, but will not likely pay a high royalty rate if there are acceptable alternatives with the same or similar attributes available for license at a lower rate.

Valuation of Royalty Agreements

In some instances it may be necessary to determine the value of a license agreement. Situations where this might be necessary include purchase price allocations, formation of a new entity (such as a joint venture) where the license agreement is assigned by one of the parties as its initial contribution, bankruptcy, termination of a licensing agreement, or sale of the licensing rights, among others. Though a complete discussion of valuation methodologies is beyond the scope of this chapter, the following is a high level overview of some of the more common methodologies to valuation and key considerations therein.

Income Approach

Any income producing asset can be valued with respect to its income generating capacity. Because royalty agreements have a fairly predictable royalty stream and a finite life, an income approach to valuation is generally used. Under the simplest variation of this approach expected future royalties over the remaining life of the agreement are discounted to their present value using a risk adjusted rate of return or discount rate. This rate of return is set at

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a level commensurate with the risk of realizing the projected royalty stream. Uncertain royalty streams will have a higher discount rate and reasonably certain royalty streams will have a lower discount rate.

To demonstrate the mechanics of this approach, assume a royalty arrangement calling for a royalty rate of 10% on sales of a specific product payable at year end over the next 3 years. Assume further that sales of the product are expected to total \$1 million in each of the next three years. Based on the risk profile of the projected sales, a qualified appraiser has determined that a 25% rate of return is appropriate.

	Year 1	Year 2	Year 3
Expected Product Revenue (000s)	\$1,000	\$1,000	\$1,000
Royalty Rate	10%	10%	10%
Royalty Income	100	100	100
Taxes @ 40%	(40)	(40)	(40)
After Tax Royalty Income	60	60	60
Present Value Factor @ 25%	0.800	0.640	0.512
Present Value of Royalty Income	48.00	38.40	30.70
Value of Royalty Agreement (sum of above)	\$117.10		

In this example, the present value factor is calculated as $1 / (1 + \text{rate of return})^{\text{time}}$, where time equals the number of years in the future (i.e., year 2 = $1 / (1.25)^2$). Excluding consideration of any additional factors, the value of the royalty agreement in this example is \$117,100. As suggested, this is an oversimplified example, and each royalty agreement must be valued in context, giving proper consideration to all elements that contribute to value.

Market Approach

The market approach is premised on the idea that the value of an asset can be estimated by drawing reference to the prices paid for other assets with similar characteristics. The challenge to this approach, and especially with intellectual property assets, is finding truly comparable assets. Transactional data related to the prices paid for licensing agreements is somewhat limited, and even when a sufficient volume of data is available, it is highly unlikely that the underlying license agreement contains substantially all of the provisions of the subject agreement or an underlying asset of substantially the same nature.

Cost (or Asset Approach)

The cost approach is rooted in the concept of replication. Value under this approach is estimated with reference to the actual cost to create the asset or by estimating the cost of reproduction or replacement of the asset. For license agreements, the cost approach has limited application as the primary cost consideration pertains to the underlying asset subject to the license and not the license itself. Additionally, the rights associated with a license are generally less than those associated with full ownership of an asset, and the cost approach may significantly overstate value. However, there are circumstances where the value of the license may be determined in this manner. The question the appraiser must ask is "but for the license, what would it cost the licensee to develop their own non-infringing alternative to the licensed asset." Assuming a non-infringing alternative is feasible, the appraiser would then attempt to estimate the indirect costs (man-hours, overhead costs, etc), direct costs (materials, equipment, lab costs, etc), and the opportunity costs (time to recreate the asset vs. licensing it now).

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1. A corporate integrity agreement, or CIA, is an agreement entered into between the OIG and the subject of an investigation typically as one component of a settlement agreement. A CIA stipulates certain actions and/or constraints which the subject company must comply with on a prospective basis.
2. Section 1128B(b) of the Act (42 U.S.C. 1320a-7b(b))(2003)
3. Commonly compared to "medical director" type arrangements in the hospital setting.
4. *Qui tam* lawsuits are initiated by a third party on behalf of the government. These actions are generally brought by whistleblowers under the federal False Claims Act.
5. The term "immediate family member" includes a husband or wife, birth or adoptive parent, child or sibling, father-in-law, mother-in-law, brother in-law, sister-in-law, grandparent or grandchild.
6. Designated health services include: radiology and other imaging services (MRI, CT and ultrasound); physical therapy; occupational therapy; radiation therapy; durable medical equipment; parenteral and enteral nutrients, equipment and supplies; prosthetics, orthotics and prosthetic devices and supplies; home health services; outpatient prescription drugs; and inpatient and outpatient hospital services. *Note that this listing of designated health services is not intended to be exhaustive, as the government has expanded the list on several occasions.*
7. Under the Phase III rule (2007), a physician "stands in the shoes" of his/her "physician organization" for purposes of analyzing financial relationships. A physician who "stands in the shoes" of his/her physician organization is deemed to have the same compensation arrangement (with the same parties and on the same terms) as the physician organization itself.
8. From CMS Phase III commentary (42 C.F.R. § 411.357(d)).
9. Department of Justice data is actually very conservative, as it does *not* include billions of dollars in civil recoveries returned to the states or criminal fines imposed as a direct consequence of False Claims Act filings and prosecutions.
10. The OIG has the authority to pursue violations of the anti-kickback statute under a provision of the Civil Monetary Penalties Law (CMP). In kickback cases, CMP remedies include monetary penalties of up to \$50,000 for each act, including any offer, payment, solicitation or receipt of remuneration. In addition, under CMP, violators can be assessed up to three times the amount of remuneration, and face exclusion in federal healthcare programs.
11. Failure to comply with a safe harbor provision does not mean that an arrangement is illegal. Compliance with safe harbors is voluntary, and arrangements that do not comply with a safe harbor must be analyzed on a case-by-case basis for compliance with the anti-kickback statute. The reader should be sure to engage the advice of appropriate counsel before consummating a specific transaction.
12. 42 CFR §411.351 (as set forth by the Centers for Medicare and Medicaid Services with respect to physicians' referrals to health care entities with which they have financial relationships). Furthermore, this definition is consistent with similar fair market value guidance related to the Anti-Kickback Statute (42 U.S.C. §1320a-7b) and with the definition relied upon by the Internal Revenue Services. See, for example, Treas. Reg. 53.4958 et seq.
13. See article entitled *Artificial-Joint Makers Settle Kickback Case*, New York Times, September 28, 2007, and the agreements between the U.S. Department of Justice and Biomet, DePuy Orthopedics, Zimmer Holdings, Stryker Orthopedics, and Smith and Nephew.
14. *Georgia Pacific Corporation v. United States Plywood Corporation*, 318 F. Supp. 1116, 166 U.S.P.Q. 235, May 28, 1970.
15. Fair market value is defined in the International Glossary of Business Valuation Terms as "*the price, expressed in terms of cash equivalents, at which property would change hands between a hypothetical willing and able buyer and a hypothetical willing and able seller, acting at arms length in an open and unrestricted market, when neither is under compulsion to buy or sell and when both have reasonable knowledge of the relevant facts.*"
16. Robert Goldscheider is a specialist & recognized authority on licensing. His calculations performed in the 1950s laid the ground work for the "25% rule" now frequently referred to as the Goldscheider rule.