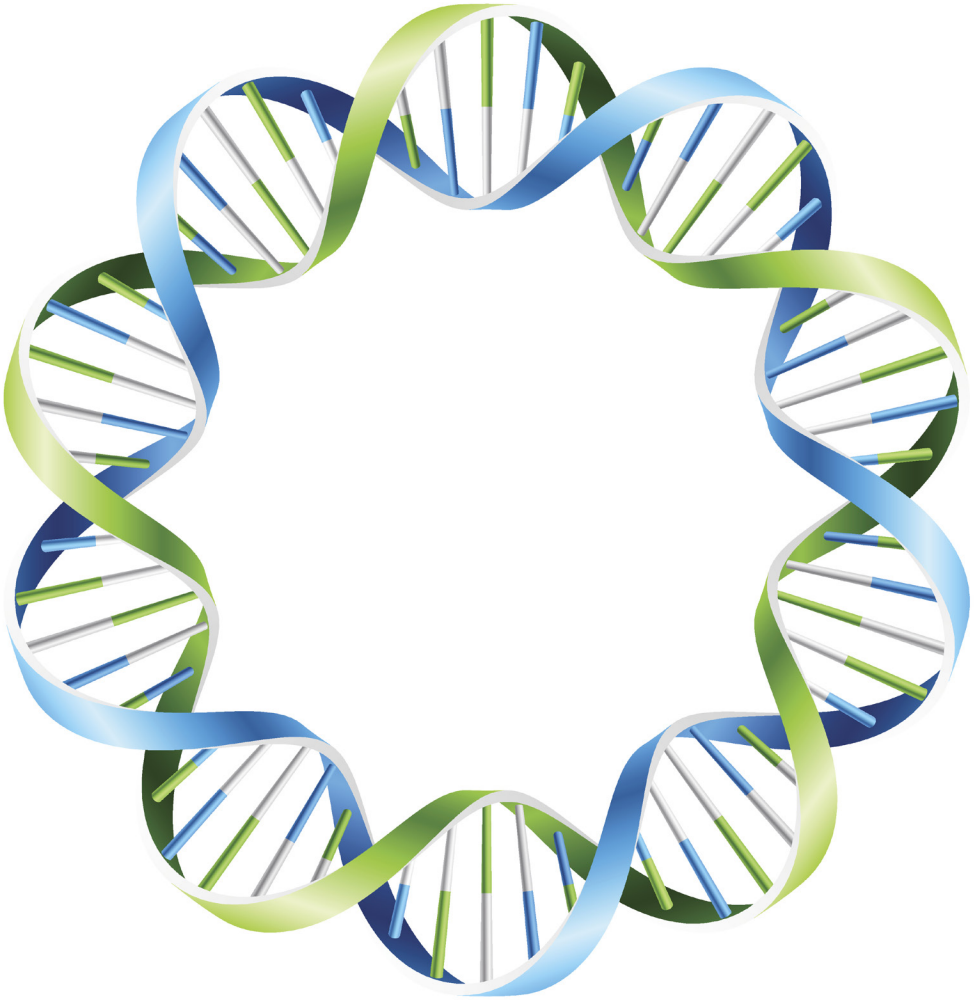
Deloitte.



Life Sciences

Accounting and Financial Reporting Update — Interpretive Guidance on Contingencies

March 2019

Contacts

If you have any questions about this publication or ways in which we can help your organization, please contact the following Deloitte industry specialists.

Jeff Ellis
U.S. Audit Leader — Life Sciences and Health Care
Life Sciences Industry Professional Practice Director
Deloitte & Touche LLP
+1 412 338 7204
jeellis@deloitte.com

Dennis Howell
Senior Consultation Partner, Accounting and Reporting Services
Life Sciences Deputy Industry Professional Practice Director
Deloitte & Touche LLP
+1 203 761 3478
dhowell@deloitte.com

Preface

March 2019

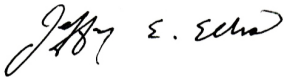
To our clients, colleagues, and other friends:

The life sciences industry represents entities that discover, develop, and manufacture health care products. Such entities include pharmaceutical manufacturers; biotechnology companies; medical device, diagnostic, and medical equipment manufacturers; and service companies such as drug distributors, contract research organizations (CROs), contract manufacturing organizations (CMOs), and health technology companies.

Finance and accounting professionals in the industry face complex issues and must exercise significant judgment in applying existing rules related to research and development (R&D) costs, acquisitions and divestitures, consolidation, contingencies, revenue recognition, income taxes, financial instruments, and financial statement presentation and disclosure. The full life sciences accounting and financial reporting update, our 10th edition, addresses these and other topics affecting the industry in 2019. It includes updated interpretive guidance as well as new sections that discuss initial public offerings (IPOs), accounting considerations for health technology companies, and the latest developments in standard setting. In addition, it discusses the outlook for the life sciences industry in 2019.

Appendix A lists the titles of standards and other literature we cited, and Appendix B defines the abbreviations we used.

Sincerely,



Jeff Ellis
U.S. Audit Leader — Life Sciences and Health Care
Life Sciences Industry Professional
Practice Director
Deloitte & Touche LLP

Dennis Howell
Senior Consultation Partner, Accounting
and Reporting Services
Life Sciences Deputy Industry Professional
Practice Director
Deloitte & Touche LLP

Contents

Chapter 1 — 2019 Industry Outlook Summary
Chapter 2 — Revenue Recognition
Chapter 3 — Research and Development
Chapter 4 — Acquisitions and Divestitures
Chapter 5 — Consolidation
Chapter 6 — Contingencies
Chapter 7 — Statement of Cash Flows
Chapter 8 — Income Taxes
Chapter 9 — Compensation
Chapter 10 — Financial Instruments
Chapter 11 — Leases
Chapter 12 — Initial Public Offerings
Chapter 13 — Other Accounting and Financial Reporting Topics
Appendix A — Titles of Standards and Other Literature
Appendix B — Abbreviations

Chapter 6 — Contingencies

6.1 Introduction

ASC 450 defines a contingency as an "existing condition, situation, or set of circumstances involving uncertainty . . . that will ultimately be resolved when . . . future events occur or fail to occur." In the life sciences industry, contingencies often arise as a result of product liability issues; patent litigation cases, such as suits filed against the entity for patent infringement (e.g., generic at-risk launches); and compliance issues related to pricing, promotions, or manufacturing standards. In addition, for biotech and pharmaceutical firms, environmental issues and remediation proceedings have been the subject of considerable public and legislative discussion and initiatives. As a result, accounting standard setters such as the FASB, AICPA, and SEC have emphasized the accounting for and disclosure of environmental liabilities in the financial statements.

In the life sciences industry, a single event could trigger multiple contingencies or other elements, requiring an entity to separately evaluate each element to determine its appropriate recognition, measurement, and classification. For example, a regulatory action may result in the incurrence of incremental costs related to product recalls, leading to a change in product strategy, adjustments to customer sales allowances, or other events. Further, a litigation settlement may contain multiple elements, including cash payments, required future services, rights to IP, and other agreements or concessions between the parties.

The accounting for and disclosures about contingencies under ASC 450 differ depending on whether the contingency could result in a gain or a loss. In addition to providing general disclosure guidance on both gain and loss contingencies, ASC 450 discusses specific application of the guidance to unasserted claims, litigation, and events occurring after the date of the financial statements but before their issuance, all of which are common in the life sciences industry.

ASC 450 defines a loss contingency as an "existing condition, situation, or set of circumstances involving uncertainty as to possible loss to an entity that will ultimately be resolved when one or more future events occur or fail to occur." Accrual of an estimated loss contingency through a charge against earnings is required if it is probable that an asset has been impaired or a liability has been incurred as of the date of the financial statements and the amount of the loss can be reasonably estimated. If the estimated amount of loss is within a range of amounts, and some amount within the range of loss appears to be a better estimate than any other amount within the range, entities must accrue that amount. If no amount within the range of loss is a better estimate than any other amount, entities must accrue the minimum amount within that range of loss. Disclosure of the nature of the accrued loss

and, in some circumstances, the amount accrued may be required so that the financial statements are not misleading. With respect to unrecognized loss contingencies, ASC 450-20-50-3 and 50-4 note the following:

ASC 450-20

50-3 Disclosure of the contingency shall be made if there is at least a reasonable possibility that a loss or an additional loss may have been incurred and either of the following conditions exists:

a. An accrual is not made for a loss contingency because any of the conditions in paragraph 450-20-25-2 are not met.

b. An exposure to loss exists in excess of the amount accrued pursuant to the provisions of paragraph 450-20-30-1.

Examples 1–3 (see paragraphs 450-20-55-18 through 55-37) illustrate the application of these disclosure standards.

50-4 The disclosure in the preceding paragraph shall include both of the following:

a. The nature of the contingency

b. An estimate of the possible loss or range of loss or a statement that such an estimate cannot be made.

A gain contingency arises if the outcome of future events may result in a possible gain or benefit to an entity (e.g., pending litigation whose outcome would result in a benefit). Unlike a loss contingency, a gain contingency is usually not reflected in the financial statements and should not be recorded in the financial statements before the contingency is realized. However, as stated in ASC 450-30-50-1, "[a]dequate disclosure shall be made of a contingency that might result in a gain, but care shall be exercised to avoid misleading implications as to the likelihood of realization."

6.2 Industry Issues

The Q&As below discuss guidance on contingency-related topics that frequently affect life sciences entities.

Q&A 6-1 Product Recalls

Life sciences entities may be subject to recalls on their products (e.g., medical devices, pharmaceutical drugs). While some product recalls are voluntary (e.g., the drug manufacturer has chosen to take the drug off the shelves or notified consumers and doctors to stop using the product or return it), other recalls may be required by the FDA or other regulators.

Question

How should the liability recognition criteria of ASC 450-20-25 be applied to a product recall obligation?

Answer

When the guidance in ASC 450-20 is applied to product recalls, the obligating event triggering liability recognition is the announcement of a recall. Except as provided for in a warranty arrangement, an entity has no legal obligation or duty associated with product design or manufacturing defects after the product is sold. Because there is no legal obligation, there is no event that gives rise to a probable loss until a recall is announced voluntarily or is mandated by regulators.

Q&A 6-2 Offers to Settle Litigation

One of the major uncertainties in the life sciences industry is the risk of litigation. Class actions, individual suits, and actions brought by government agencies are not uncommon, and such contingencies may need to be accounted for or disclosed in the financial statements (e.g., a potential future obligation related to an uncertain amount resulting from past activities). With respect to pending or threatened litigation, ASC 450 requires the accrual of a loss contingency if certain criteria are met. Entities will often make offers to settle existing litigation; the accounting for the offer should be based on existing facts and circumstances associated with the litigation and related settlement.

Question

Does an offer by management to settle litigation need to be accrued in the financial statements?

Answer

An offer to settle litigation creates a strong presumption that it is probable that a liability has been incurred. The settlement offer presumably establishes a low end of the range under ASC 450-20-30-1, resulting in accrual of a liability. Withdrawal of a settlement offer before acceptance and before issuance of the financial statements generally would not change this conclusion since the existence of the offer indicates that a probable obligation existed as of the date of the financial statements.

In limited circumstances, it might be possible to overcome the presumption that an offer to settle litigation triggers accrual of a liability and establishes a low end of the range. However, rebutting the presumption should be a high hurdle to overcome and should be based on persuasive evidence to the contrary. At a minimum, the evidence would need to substantiate that it is remote that (1) the offer will be accepted and (2) further negotiations will lead to an out-of-court settlement. One form of such evidence could be an unequivocal representation from legal counsel. An entity that believes that the presumption has been overcome should consider consulting with its accounting advisers.

Example

Company X is in the medical device business. Over the past year, X has been named as the defendant in a lawsuit alleging personal injury resulting from use of one of its surgical devices. After year-end, but before issuance of the annual financial statements, X offers to settle the litigation for $1 million. Management of X contends that this offer was made solely to accelerate the process of resolving the dispute. The plaintiff has not responded to the offer. Company X believes that if the matter ultimately goes to trial, the plaintiff will not prevail with its claim.

The offer to settle is evidence that it is probable that a liability has been incurred as of the date of the financial statements and that the amount of the loss can be reasonably estimated. Company X should consider the guidance in ASC 450-20-30-1 in determining the appropriate amount to accrue. The amount of the offer establishes the low end of the range. If this amount is accrued, X must also disclose any additional exposure to loss in its financial statements if the disclosure requirements in ASC 450-20-50-3 are met.

Connecting the Dots

An entity should carefully consider all facts and circumstances when assessing whether an "offer" has been extended to settle litigation. For example, when the offer hinges on a counterparty's performance of certain actions to which the entity believes the counterparty is not likely to agree, the entity may conclude that an offer has not been extended.

Q&A 6-3 Accounting for Litigation Settlements When One or More Elements Exist

While some legal settlements in the life sciences industry involve only a single element (e.g., a claim or lawsuit over patent infringement), challenges often arise when a litigation settlement contains multiple elements.

Question

How should an entity account for a litigation settlement involving multiple elements?

Answer

An entity should identify each item given and received in the arrangement and determine whether such items should be recognized. In a speech delivered at the 2007 AICPA Conference on Current SEC and PCAOB Developments, Eric West, associate chief accountant in the SEC's Office of the Chief Accountant, addressed how an entity should account for litigation settlements containing more than one element:

> **Elements of the Arrangement**
>
> To properly account for this arrangement, a company must identify each item given and received and determine whether those items should be recognized. We have found that errors generally occur when registrants don't fully consider the nature of each item. . . .
>
> **Allocating Consideration to Each Item**
>
> An additional challenge that may arise when accounting for a litigation settlement is determining the proper allocation of consideration among the recognizable elements. While EITF [Issue] 00-21 [ASC 605-25] was written for multiple element revenue arrangements, we believe that its allocation guidance is also useful to determine how to allocate consideration paid in a multiple element legal settlement. In this regard, we believe that it would be acceptable to value each element of the arrangement and allocate the consideration paid to each element using relative fair values. To the extent that one of the elements of the arrangement just can't be valued, we believe that a residual approach may be a reasonable solution. In fact, we have found that many companies are not able to reliably estimate the fair value of the litigation component of any settlement and have not objected to judgments made when registrants have measured this component as a residual. In a few circumstances companies have directly measured the value of the litigation settlement component. [Footnote omitted]

Example

Mr. West gave the following example of a litigation settlement:

> Assume a company pays cash and conveys licenses to a plaintiff in order to settle a patent infringement and misappropriation of trade secrets claim. In exchange for the payment and licenses given, the company receives a promise to drop the patent infringement lawsuit, a covenant not to sue with respect to the misappropriation of trade secrets claim, and a license to use the patents subject to the litigation.

In this arrangement, the items given include cash and licenses, and the items received include the promise to drop the patent infringement lawsuit, the covenant not to sue, and the license to use the patents. After identifying these items and determining whether to recognize them, the company must use the relative fair value method or another approach (e.g., the residual value approach if one of the elements cannot be valued) to determine the proper allocation of consideration among the recognizable elements. Mr. West further clarified:

> In the fact pattern that I just described, the company may be able to calculate the value of the settlement by applying a royalty rate to the revenues derived from the products sold using the patented technology during the infringement period. Admittedly, this approach requires judgment and we are willing to consider reasonable judgments.

Connecting the Dots

In addition to determining the allocation of consideration to the recognized elements, life sciences entities are also encouraged to consider the appropriate classification of litigation settlements within their income statement, particularly when the plaintiff is a customer of the entity. As noted in Mr. West's speech:

> In the fact pattern that I've talked about so far it would be appropriate to record the consideration allocated to the litigation within operating expenses since the company did not have a prior relationship with the plaintiff. However, we believe that a different answer may result if the plaintiff is also a customer of the defendant. Assume a company settles a claim for over billing its customers for an amount that is in excess of the amounts they over billed. The company believed that the excess payment was necessary to preserve the customer relationship and had induced the customer to settle the claim. In this case we do not believe that classification of the entire payment as a settlement expense would be consistent with existing GAAP. Since the settlement payment was made to the company's customers, we believe that the payment is within the scope of EITF [Issue] 01-9. As you may know, this EITF [Issue] addresses the accounting for consideration given by a vendor to a customer. The scope is broadly written and includes all consideration given by a vendor to a customer. It also requires that cash consideration paid be classified as a reduction of revenues unless the vendor receives an identifiable benefit and the fair value of that benefit can be reliably measured. In this fact pattern, we believe that the excess amount paid to the customer represents both a payment to retain the customer and settle the litigation. However, if the company is unable to determine the fair value of each of these components, we believe that EITF [Issue] 01-9 requires the entire payment to be classified as a reduction of revenues. Had the company been able to directly value the litigation, classification of that portion of the settlement payment as an expense may have been appropriate. [Footnote omitted]

In certain circumstances, life sciences entities may need to exercise significant judgment in determining whether a litigation settlement involves a customer. For example, when the plaintiff is a governmental entity and the life sciences entity participates in governmental programs (e.g., Medicare or Medicaid), the life sciences entity (1) should consider whether the payment made to the governmental entity represents a payment made to a customer and (2) is encouraged to document its judgments related to income statement classification of the settlement contemporaneously.

Q&A 6-4 Accounting for Liabilities When Demand for Payment Is Not Probable, and Whether Legally or Contractually Required Liabilities Can Be Derecognized on the Basis of a Probability Assessment

In the life sciences industry, obligations to a third party, such as a customer or patent holder, may arise as a result of a law or contract that may be unknown to the third party. Such obligations (e.g., a royalty liability required by contract for the use of a patent) should not be accounted for as loss contingencies under ASC 450-20 even if the third party is unaware of the obligation and is unlikely to demand payment. Further, if an entity believes that a liability for which payment is required by law or contract will ultimately be settled for less than the stated legal obligation, the entity should not derecognize the liability (or a portion of the liability) until the liability has been extinguished in accordance with ASC 405-20-40-1.

Question 1

Is a liability for which payment is required by law or contract a loss contingency accounted for under ASC 450-20 if it is uncertain whether the creditor is aware of the obligation and will demand payment?

Answer

No. In general, the probability of payment is irrelevant if settlement of the liability is required by law or contract. That is, other than deferred revenues, liabilities established by law or contract should be recorded at their stated amounts unless there is guidance under U.S. GAAP that requires otherwise.

Paragraph 36 of FASB Concepts Statement 6 states that a liability has the following three essential characteristics:

- "[I]t embodies a present duty or responsibility to one or more other entities that entails settlement by probable future transfer or use of assets at a specified or determinable date, on occurrence of a specified event, or on demand."
- "[T]he duty or responsibility obligates a particular entity, leaving it little or no discretion to avoid the future sacrifice."
- "[T]he transaction or other event obligating the entity has already happened."

If an entity is required by current laws, regulations, or contracts to make a future payment associated with an event that has already occurred, that event imposes a present duty upon the entity. An entity's uncertainty about whether performance of an obligation will be required in the future does not allow the entity to choose to avoid the future sacrifice or relieve it of the obligation.

When the obligating event has occurred, the probability of payment is irrelevant to the determination of whether a contractual or legal obligation is a liability or a loss contingency. That is, when the obligating event has occurred, the entity has incurred a liability; accordingly, there is no contingency. This conclusion is supported by analogy to paragraph B21 of FASB Interpretation 48 (superseded), which states that the Board "also considered the guidance in paragraphs 26 and 36 of Concepts Statement 6 on the characteristics of an asset and a liability" and "noted that consideration of examination risk is not consistent with the characteristics of an asset or a liability."

In this context, "examination risk" represents the risk that a taxing authority would examine a particular tax position. In the Background Information and Basis for Conclusions of FASB Interpretation 48, the Board rejected the idea that accounts payable, for example, should be recorded on the basis of the amount that an entity would ultimately pay if the creditor filed suit to collect the liability.

This conclusion is further supported by analogy to ASC 410-20-25-15, which states that an "unambiguous requirement that gives rise to an asset retirement obligation coupled with a low likelihood of required performance still requires recognition of a liability."

In addition, a liability is not an unasserted claim or assessment under ASC 450-20 if the satisfaction of the liability is required by law or contract. The existence of the law or the contract constitutes an assertion of the claim. This conclusion is supported by analogy to paragraph B20 of FASB Interpretation 48, which states that the "Board considered the guidance on unasserted claims in paragraph 38 of Statement 5 [codified in ASC 450-20-55-14 and 55-15]" and "does not believe that guidance is applicable to tax positions because a tax return is generally required to be filed based on the provisions of tax law."

Question 2

If an entity believes that a liability that is not deferred revenue, and for which payment is required by law or contract, will ultimately be settled for less than the stated legal obligation, can the liability be derecognized on the basis of a probability assessment of whether and, if so, when the creditor will demand payment?

Answer

No. ASC 405-20-40-1 states the following (pending content effective upon adoption of ASU 2016-04 {in braces}):

> {Unless addressed by other guidance (for example, paragraphs 405-20-40-3 through 40-4 or paragraphs 606-10-55-46 through 55-49), a} A debtor shall derecognize a liability if and only if it has been extinguished. A liability has been extinguished if either of the following conditions is met:
>
> a. The debtor pays the creditor and is relieved of its obligation for the liability. Paying the creditor includes the following:
>
> 1. Delivery of cash
> 2. Delivery of other financial assets
> 3. Delivery of goods or services
> 4. Reacquisition by the debtor of its outstanding debt securities whether the securities are cancelled or held as so-called treasury bonds.
>
> b. The debtor is legally released from being the primary obligor under the liability, either judicially or by the creditor. For purposes of applying this Subtopic, a sale and related assumption effectively accomplish a legal release if nonrecourse debt (such as certain mortgage loans) is assumed by a third party in conjunction with the sale of an asset that serves as sole collateral for that debt.

Example

Company Y manufactures medical equipment and has a contractual obligation to pay, on the basis of sales volume, royalties to various patent holders. The amount of royalties paid in each period is calculated by Y. In accordance with this obligation, patent holders have the right to audit Y's sales volume, but they have rarely exercised this right.

Company Y should record a royalty liability for the full amount that it is contractually obligated to pay under the royalty agreements. The liability should be adjusted upward as sales are made and should be adjusted downward only when the liability is paid or otherwise extinguished.

The contract requires Y to make royalty payments on the basis of sales volume. Therefore, Y is under an obligation to the patent holder as the equipment is sold (i.e., Y has a present duty to the patent holder). Company Y's uncertainty about whether a patent holder will audit the sales volume does not allow it to avoid future payment. However, Y should not record a royalty liability for future sales until those sales actually occur. Further, if a patent holder cannot be located, the contractual liability should not be reduced until the liability derecognition guidance in ASC 405-20-40-1 has been met, which could be when the escheat laws for the particular jurisdiction are complied with and the obligation no longer exists.

Q&A 6-5 Events Occurring After the Date of the Financial Statements

Information that becomes available after the balance sheet date but before issuance of the financial statements may indicate that an asset was impaired, or that a liability was incurred, before the date of the financial statements. In the life sciences industry, events that occur after the balance sheet date may serve as confirmation of a condition that existed as of the balance sheet date (e.g., the settlement of litigation that arose during prior periods covered by the financial statements and for which no liability had previously been recorded).

However, events occurring after the balance sheet date, such as the passage of new legislation, may be indicative of conditions that did not exist as of the balance sheet date. Financial statement disclosures about such events are required only if omission of such disclosures would cause the financial statements to be misleading.

Question

If legislation giving rise to a liability is enacted after the balance sheet date but before issuance of the financial statements, should a liability be accrued as of the balance sheet date?

Answer

No. The enactment of a law after the balance sheet date but before issuance of the financial statements would be accounted for as a nonrecognized subsequent event (because the newly enacted law does not provide evidence about conditions that existed as of the balance sheet date). The entity should consider whether it is required to disclose the event to keep the financial statements from being misleading.

Example

Entity A, a public entity with a December 31, 20X1, year-end, operates in the pharmaceutical industry and is subject to proposed legislation that will impose an excise tax on existing branded pharmaceuticals as of June 30, 20X1. The legislation is expected to be enacted after year-end but before the issuance of the financial statements. Entity A believes that because the legislation is probable and is related to balances as of a date before the balance sheet date, a liability should be accrued. However, the obligating event in this case is the enactment of the legislation, and A did not incur a liability before this event even though the tax was assessed on preexisting branded pharmaceuticals; thus, no liability should be accrued as of December 31, 20X1. Instead, the impact of the new legislation is a nonrecognized subsequent event, and A should consider whether it is required to disclose the event to keep the financial statements from being misleading.

Q&A 6-6 Favorable Legal Settlements

Usually, financial statements do not reflect contingencies that might result in gains since reflecting such contingencies might result in the recognition of income before it is realized. Entities should provide adequate disclosures about contingencies that might result in gains and should be careful to avoid misleading implications regarding the likelihood of realization. The term "probable" is relevant to the accounting for a loss contingency, but it is irrelevant to the accounting for a gain contingency. Realization must be assured beyond a reasonable doubt before a gain contingency can be recognized in the financial statements. Therefore, substantially all uncertainties, if any, about the timing and amount of realization of gain contingencies should be resolved before the contingencies are recognized in the financial statements.

Question

Upon the receipt of a favorable verdict in a court case, is recognition of a gain contingency appropriate?

Answer

Because of the numerous uncertainties inherent in a litigation proceeding, gain contingencies resulting from legal settlements generally cannot be recognized in income until cash or other forms of payment are received. This threshold for recognition often results in the deferral of a gain even after a court rules in favor of a plaintiff.

Example

Company R was a plaintiff in a class action lawsuit against several drug manufacturers. After a lengthy appeals process, a settlement was reached. The funds were placed in an escrow account since an agreement had not been reached regarding the allocation of the settlement between the attorneys and each respective plaintiff. Because R does not know the timing or amount of cash to be received, gain recognition is inappropriate at this point.

6.3 SEC Comment Letter Themes Related to Contingencies

The SEC staff continues to closely monitor SEC registrants' contingency disclosures, and it comments when such disclosures do not comply with U.S. GAAP or SEC rules and regulations.

The staff has continued to comment on:

- Lack of specificity regarding the nature of the matter.
- Lack of quantification of amounts accrued, if any, and possible loss or range of loss (or disclosure about why such an estimate cannot be made).
- Lack of disclosure or insufficient detail about what triggered a significant current-period accrual for a contingency when no loss or a significantly lower amount was accrued in prior periods (i.e., the lack of "early warning" disclosures in prior periods).
- Insufficient detail about judgments and assumptions underlying significant accruals.
- Insufficient detail about (and untimely reporting of) new developments related to loss contingencies and the effect of such developments on current and future periods.
- Inconsistency among disclosures in the footnotes, in other sections of the filing (e.g., risk factors and legal proceedings), and outside the filing (e.g., in press releases and earnings calls). In addition, if different registrants are parties to a claim, the SEC staff may also review the counterparty's filings and comment if the information is not consistent.
- Use of unclear language in disclosures (e.g., not using terms that are consistent with accounting literature, such as "probable" or "reasonably possible") and failure to consider the disclosure requirements in ASC 450, SAB Topic 5.Y, and SEC Regulation S-K, Item 103.
- Lack of disclosure of an accounting policy related to accounting for legal costs (when material) and uncertainties in loss contingency recoveries, including (1) whether ranges of reasonably possible losses are disclosed gross or net of anticipated recoveries from third parties, (2) risks regarding the collectibility of anticipated recoveries, and (3) the accounting policy for uncertain recoveries.

Below are examples of certain SEC staff comments that registrants in the life sciences industry and other industries have received regarding their accounting for contingencies. For more information about SEC comment letter themes that pertain to the life sciences industry, see Deloitte's *A Roadmap to SEC Comment Letter Considerations, Including Industry Insights*.

6.3.1 Loss Contingencies

Examples of SEC Comments
• With respect to the cyber-security incident and related assessments and litigation, please tell us your consideration of the requirement in ASC 450-20-50-4.b. to disclose an estimate of the possible loss or range of loss or to disclose that such an estimate cannot be made. • We note that you have evaluated your potential exposure related to [Matter A] and have established a loss contingency of $[X] to cover your probable and estimable liabilities as of September 30, 2016. If there is at least a reasonable possibility that a loss exists in excess of the amount accrued, please revise to either disclose an estimate (or, if true, state that the estimate is immaterial in lieu of providing quantified amounts) of the additional loss or range of loss or state that such an estimate cannot be made. Please refer to ASC 450-20-50-3 to 4 and include your proposed disclosures in your response.

The SEC staff often asks about estimates of reasonably possible losses or comments when a registrant omits disclosure of a loss or range of losses because its estimates lack "precision and confidence." If an estimate of the loss or range of losses cannot be made, the staff expects registrants to (1) disclose, in accordance with ASC 450-20-50-4, that such an estimate cannot be made and (2) demonstrate that they at least attempted to estimate the loss or range of losses before concluding that an estimate cannot be made. In such cases, the staff has commented that registrants should disclose the specific factors that limited their ability to reasonably estimate the loss or range of losses and has asked about registrants' quarterly procedures related to such estimates. The factors disclosed should be specific to the loss contingency in question and could include representations that (1) claims do not specify an amount of damages, (2) there are a large number of plaintiffs, or (3) the case is in its early stages.

Further, if a registrant discusses a potential contingency in its earnings calls, the SEC staff is likely to seek more information about the contingency and to inquire about whether the related disclosures are appropriate. The staff encourages registrants to clearly disclose the "full story" regarding their loss contingencies because recognition of such contingencies requires a high degree of professional judgment. Further, the staff has noted that disclosures related to loss contingencies should be continually evaluated over time as facts and circumstances change.

The SEC staff may also ask about (1) the basis for a registrant's accrual (e.g., factors supporting an accrual, such as trends in claims received and rejected), (2) the timing of a loss contingency's recognition, and (3) the disclosure of a loss contingency. In addition, when a material settlement is disclosed during the period, the staff may review prior-period disclosures to determine whether such disclosures were appropriate (i.e., whether the registrant should have provided early-warning disclosures about the possibility of incurring or settling a loss in future periods to help users understand these risks and how they could potentially affect the financial statements) or whether an accrual should have been recognized in a prior period.

6.3.2 Litigation Contingencies

In addition to complying with ASC 450, public entities must separately meet the requirements of SEC Regulation S-K, Item 103, when disclosing litigation matters because while those requirements are similar to the requirements of ASC 450, they are not identical. Also, to address concerns related to a registrant's contention that providing too much information may be detrimental to efforts to litigate or settle matters, the SEC staff has indicated that registrants do not need to separately disclose each asserted claim; rather, they may aggregate asserted claims in a logical manner as long as the disclosure complies with ASC 450.

Appendix A — Titles of Standards and Other Literature

The standards and other literature below were cited or linked to in this publication.

AICPA Literature

Accounting and Valuation Guide

Assets Acquired to Be Used in Research and Development Activities

Valuation of Privately-Held-Company Equity Securities Issued as Compensation

Audit and Accounting Guide

Revenue Recognition

Issues Paper

Identification and Discussion of Certain Financial Accounting and Reporting Issues Concerning LIFO Inventories

Other

AICPA Technical Practice Aid, Section 2260.03, "Other Assets; Legal Expenses Incurred to Defend Patent Infringement Suit"

FASB Literature

ASC Topics

ASC 205, *Presentation of Financial Statements*

ASC 210, *Balance Sheet*

ASC 220, *Income Statement — Reporting Comprehensive Income*

ASC 230, *Statement of Cash Flows*

ASC 235, *Notes to Financial Statements*

ASC 250, *Accounting Changes and Error Corrections*

ASC 260, *Earnings per Share*

ASC 280, *Segment Reporting*

ASC 310, *Receivables*

ASC 320, *Investments — Debt and Equity Securities*

ASC 321, *Investments — Equity Securities*

ASC 323, *Investments — Equity Method and Joint Ventures*

ASC 325, *Investments — Other*

ASC 326, *Financial Instruments — Credit Losses*

ASC 330, *Inventory*

ASC 350, *Intangibles — Goodwill and Other*

ASC 360, *Property, Plant, and Equipment*

ASC 405, *Liabilities*

ASC 410, *Asset Retirement and Environmental Obligations*

ASC 420, *Exit or Disposal Cost Obligations*

ASC 450, *Contingencies*

ASC 470, *Debt*

ASC 480, *Distinguishing Liabilities From Equity*

ASC 505, *Equity*

ASC 605, *Revenue Recognition*

ASC 606, *Revenue From Contracts With Customers*

ASC 610, *Other Income*

ASC 715, *Compensation — Retirement Benefits*

ASC 718, *Compensation — Stock Compensation*

ASC 720, *Other Expenses*

ASC 730, *Research and Development*

ASC 740, *Income Taxes*

ASC 805, *Business Combinations*

ASC 808, *Collaborative Arrangements*

ASC 810, *Consolidation*

ASC 815, *Derivatives and Hedging*

ASC 820, *Fair Value Measurement*

ASC 825, *Financial Instruments*

ASC 830, *Foreign Currency Matters*

ASC 840, *Leases*

ASC 842, *Leases*

ASC 845, *Nonmonetary Transactions*

ASC 850, *Related Party Disclosures*

ASC 855, *Subsequent Events*

ASC 915, *Development Stage Entities*

ASC 958, *Not-for-Profit Entities*

ASC 985, *Software*

ASUs

2010-20, *Receivables (Topic 310): Disclosures About the Credit Quality of Financing Receivables and the Allowance for Credit Losses*

2010-27, *Other Expenses (Topic 720): Fees Paid to the Federal Government by Pharmaceutical Manufacturers* — a consensus of the FASB Emerging Issues Task Force

2011-06, *Other Expenses (Topic 720): Fees Paid to the Federal Government by Health Insurers* — a consensus of the FASB Emerging Issues Task Force

2014-02, *Intangibles — Goodwill and Other (Topic 350): Accounting for Goodwill* — a consensus of the Private Company Council

2014-09, *Revenue From Contracts With Customers (Topic 606)*

2014-10, *Development Stage Entities (Topic 915): Elimination of Certain Financial Reporting Requirements, Including an Amendment to Variable Interest Entities Guidance in Topic 810,* Consolidation

2014-15, *Presentation of Financial Statements — Going Concern (Subtopic 205-40): Disclosure of Uncertainties About an Entity's Ability to Continue as a Going Concern*

2014-16, *Derivatives and Hedging (Topic 815): Determining Whether the Host Contract in a Hybrid Financial Instrument Issued in the Form of a Share Is More Akin to Debt or to Equity* — a consensus of the FASB Emerging Issues Task Force

2015-14, *Revenue From Contracts With Customers (Topic 606): Deferral of the Effective Date*

2015-17, *Income Taxes (Topic 740): Balance Sheet Classification of Deferred Taxes*

2016-01, *Financial Instruments — Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities*

2016-02, *Leases (Topic 842)*

2016-04, *Liabilities — Extinguishment of Liabilities (Subtopic 405-20): Recognition of Breakage for Certain Prepaid Store-Valued Products* — a consensus of the FASB Emerging Issues Task Force

2016-08, *Revenue From Contracts With Customers (Topic 606): Principal Versus Agent Considerations (Reporting Revenue Gross Versus Net)*

2016-09, *Compensation — Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting*

2016-10, *Revenue From Contracts With Customers (Topic 606): Identifying Performance Obligations and Licensing*

2016-11, *Revenue Recognition (Topic 605) and Derivatives and Hedging (Topic 815): Rescission of SEC Guidance Because of Accounting Standards Updates 2014-09 and 2014-16 Pursuant to Staff Announcements at the March 3, 2016 EITF Meeting*

2016-12, *Revenue From Contracts With Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients*

2016-13, *Financial Instruments — Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*

2016-15, *Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments* — a consensus of the FASB Emerging Issues Task Force

2016-16, *Income Taxes (Topic 740): Intra-Entity Transfers of Assets Other Than Inventory*

2016-17, *Consolidation (Topic 810): Interests Held Through Related Parties That Are Under Common Control*

2016-18, *Statement of Cash Flows (Topic 230): Restricted Cash* — a consensus of the FASB Emerging Issues Task Force

2016-20, *Technical Corrections and Improvements to Topic 606,* Revenue From Contracts With Customers

2017-01, *Business Combinations (Topic 805): Clarifying the Definition of a Business*

2017-04, *Intangibles — Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment*

2017-05, *Other Income — Gains and Losses From the Derecognition of Nonfinancial Assets (Subtopic 610-20): Clarifying the Scope of Asset Derecognition Guidance and Accounting for Partial Sales of Nonfinancial Assets*

2017-07, *Compensation — Retirement Benefits (Topic 715): Improving the Presentation of Net Periodic Pension Cost and Net Periodic Postretirement Benefit Cost*

2017-11, *Earnings per Share (Topic 260); Distinguishing Liabilities From Equity (Topic 480); Derivatives and Hedging (Topic 815): (Part I) Accounting for Certain Financial Instruments With Down Round Features, (Part II) Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests With a Scope Exception*

2017-12, *Derivatives and Hedging (Topic 815): Targeted Improvements to Accounting for Hedging Activities*

2017-13, *Revenue Recognition (Topic 605), Revenue From Contracts With Customers (Topic 606), Leases (Topic 840), and Leases (Topic 842): Amendments to SEC Paragraphs Pursuant to the Staff Announcement at the July 20, 2017 EITF Meeting and Rescission of Prior SEC Staff Announcements and Observer Comments* (SEC Update)

2017-14, *Income Statement — Reporting Comprehensive Income (Topic 220), Revenue Recognition (Topic 605), and Revenue From Contracts With Customers (Topic 606)* (SEC Update)

2018-01, *Leases (Topic 842): Land Easement Practical Expedient for Transition to Topic 842*

2018-02, *Income Statement — Reporting Comprehensive Income (Topic 220): Reclassification of Certain Tax Effects From Accumulated Other Comprehensive Income*

2018-03, *Technical Corrections and Improvements to Financial Instruments — Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities*

2018-07, *Compensation — Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting*

2018-08, *Not-For-Profit Entities (Topic 958): Clarifying the Scope and the Accounting Guidance for Contributions Received and Contributions Made*

2018-10, *Codification Improvements to Topic 842,* Leases

2018-11, *Leases (Topic 842): Targeted Improvements*

2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework — Changes to the Disclosure Requirements for Fair Value Measurement*

2018-14, *Compensation — Retirement Benefits — Defined Benefit Plans — General (Subtopic 715-20): Disclosure Framework — Changes to the Disclosure Requirements for Defined Benefit Plans*

2018-17, *Consolidation (Topic 810): Targeted Improvements to Related Party Guidance for Variable Interest Entities*

2018-18, *Collaborative Arrangements (Topic 808): Clarifying the Interaction Between Topic 808 and Topic 606*

Concepts Statements

No. 5, *Recognition and Measurement in Financial Statements of Business Enterprises*

No. 6, *Elements of Financial Statements*

No. 8, *Conceptual Framework for Financial Reporting — Chapter 1,* The Objective of General Purpose Financial Reporting*, and Chapter 3,* Qualitative Characteristics of Useful Financial Information

Proposed ASUs

No. 2015-310, *Notes to Financial Statements (Topic 235): Assessing Whether Disclosures Are Material*

No. 2015-340, *Government Assistance (Topic 832): Disclosures by Business Entities About Government Assistance*

No. 2016-270, *Income Taxes (Topic 740) Disclosure Framework — Changes to the Disclosure Requirements for Income Taxes*

No. 2017-200, *Debt (Topic 470): Simplifying the Classification of Debt in a Classified Balance Sheet (Current Versus Noncurrent)*

No. 2017-210, *Inventory (Topic 330): Disclosure Framework — Changes to the Disclosure Requirements for Inventory*

No. 2017-280, *Consolidation (Topic 812): Reorganization*

No. 2018-300, *Codification Improvements — Financial Instruments*

No. 2019-100, *Targeted Transition Relief for Topic 326, Financial Instruments — Credit Losses*

Other FASB Proposal

Proposed Concepts Statement 2014-200, *Conceptual Framework for Financial Reporting: Chapter 8: Notes to Financial Statements*

International Standards

IFRS 3, *Business Combinations*

IFRS 11, *Joint Arrangements*

IFRS 15, *Revenue From Contracts With Customers*

IFRS 16, *Leases*

IAS 10, *Events After the Reporting Period*

IAS 20, *Accounting for Government Grants and Disclosure of Government Assistance*

IRC

Section 78, "Gross Up for Deemed Paid Foreign Tax Credit"

Section 163(j), "Interest; Limitation on Business Interest"

Section 199, "Income Attributable to Domestic Production Activities"

Section 383, "Special Limitations on Certain Excess Credits, etc."

Section 409A "Inclusion in Gross Income of Deferred Compensation Under Nonqualified Deferred Compensation Plans"

Section 422, "Incentive Stock Options"

Section 423, "Employee Stock Purchase Plans"

Section 965, "Treatment of Deferred Foreign Income Upon Transition to Participation Exemption System of Taxation"

Section 4191, "Medical Devices"

PCAOB Literature

Release No. 2017-001, *The Auditor's Report on an Audit of Financial Statements When the Auditor Expresses an Unqualified Opinion and Related Amendments to PCAOB Standards*

SEC Literature

FRM

Topic 1, "Registrant's Financial Information"

Topic 2, "Other Financial Statements Required"

Topic 3, "Pro Forma Financial Information"

Topic 7, "Related Party Matters"

Topic 9, "Management's Discussion and Analysis of Financial Position and Results of Operations (MD&A)"

Topic 10, "Emerging Growth Companies"

Interpretive Release

33-10403, *Updates to Commission Guidance Regarding Accounting for Sales of Vaccines and Bioterror Countermeasures to the Federal Government for Placement Into the Pediatric Vaccine Stockpile or the Strategic National Stockpile*

Regulation S-K

Item 103, "Business; Legal Proceedings"

Regulation S-X

Rule 1-02(w), "Definitions of Terms Used in Regulation S-X (17 CFR part 210); Significant Subsidiary"

Rule 3-05, "Financial Statements of Businesses Acquired or to Be Acquired"

Rule 3-09, "Separate Financial Statements of Subsidiaries Not Consolidated and 50 Percent or Less Owned Persons"

Rule 3-14, "Special Instructions for Real Estate Operations to Be Acquired"

Rule 4-08(g), "General Notes to Financial Statements: Summarized Financial Information of Subsidiaries Not Consolidated and 50 Percent or Less Owned Persons"

Rule 4-08(h), "General Notes to Financial Statements: Income Tax Expense"

Article 11, "Pro Forma Financial Information"

Rule 11-01 "Presentation Requirements"

SAB Topics

SAB Topic 1.M, "Financial Statements; Materiality"

SAB Topic 5.Y, "Miscellaneous Accounting; Accounting and Disclosures Relating to Loss Contingencies"

SAB Topic 11.A, "Miscellaneous Disclosure; Operating-Differential Subsidies"

SAB Topic 13, "Revenue Recognition"

SAB Topic 14.B, "Share-Based Payment; Transition From Nonpublic to Public Entity Status"

SAB Topic 14.D.1, "Certain Assumptions Used in Valuation Methods; Expected Volatility"

SAB Topic 14.D.2, "Certain Assumptions Used in Valuation Methods; Expected Term"

SAB 116, "Staff Accounting Bulletin No. 116"

Superseded Literature

EITF Issues

Issue 00-21, "Revenue Arrangements With Multiple Deliverables"

Issue 01-8, "Determining Whether an Arrangement Contains a Lease"

Issue 01-9, "Accounting for Consideration Given by a Vendor to a Customer (Including a Reseller of the Vendor's Products)"

Issue 08-6, "Equity Method Investment Accounting Considerations"

Issue 09-2, "Research and Development Assets Acquired in an Asset Acquisition"

Issue 09-4, "Seller Accounting for Contingent Consideration"

FASB Interpretations

No. 48, *Accounting for Uncertainty in Income Taxes* — an interpretation of FASB Statement No. 109

FASB Statements

No. 5, *Accounting for Contingencies*

No. 123(R), *Share-Based Payment*

No. 141(R), *Business Combinations*

No. 160, *Noncontrolling Interests in Consolidated Financial Statements* — an amendment of ARB No. 51

Appendix B — Abbreviations

Abbreviation	Description
ABO	accumulated benefit obligation
AFS	available for sale
AICPA	American Institute of Certified Public Accountants
AMT	alternative minimum tax
AOCI	accumulated other comprehensive income
API	active pharmaceutical ingredient
APIC	additional paid-in capital
ASC	FASB Accounting Standards Codification
ASR	accelerated share repurchase
ASU	FASB Accounting Standards Update
BCF	beneficial conversion feature
BEAT	base erosion anti-abuse tax
BEMTA	base erosion minimum tax amount
BOLI	bank-owned life insurance
BPD	branded prescription drug
CAM	critical audit matter
CAQ	Center for Audit Quality
CDO	chief digital officer
CECL	current expected credit loss
CFC	controlled foreign corporation
CMO	contract manufacturing organization
CODM	chief operating decision maker
COLI	corporate-owned life insurance
CRO	contract research organization
CTA	cumulative translation adjustment

Abbreviation	Description
DTA	deferred tax asset
DTL	deferred tax liability
E&P	earnings and profits
EBITDA	earnings before interest, taxes, depreciation, and amortization
EDGAR	SEC electronic data gathering, analysis, and retrieval system
EGC	emerging growth company
EITF	Emerging Issues Task Force
ESPP	employee stock purchase plan
EU	European Union
FAQ	frequently asked question
FASB	Financial Accounting Standards Board
FAST Act	Fixing America's Surface Transportation Act
FDA	Food and Drug Administration
FDII	foreign derived intangible income
FIFO	first in, first out
FOB	free on board
FRM	SEC Division of Corporation Finance Financial Reporting Manual
GAAP	generally accepted accounting principles
GILTI	global intangible low-taxed income
GPO	group purchasing organization
IAS	International Accounting Standard
IASB	International Accounting Standards Board

Abbreviation	Description
IFRS	International Financial Reporting Standard
IIR	investigator-initiated research
IP	intellectual property
IPO	initial public offering
IPR&D	in-process research and development
IRC	Internal Revenue Code
IRS	Internal Revenue Service
ISO	incentive stock option
IT	information technology
JOBS Act	Jumpstart Our Business Startups Act
LIFO	last in, first out
LLC	limited liability company
LP	limited partnership
M&A	merger and acquisition
MD&A	Management's Discussion & Analysis
MDET	medical device excise tax
MSL	medical science liaison
NFP	not-for-profit entity
NOL	net operating loss
NQSO	non-qualified stock option
NSO	nonstatutory option
OCI	other comprehensive income
OECD	Organisation for Economic Co-operation and Development
OEM	original equipment manufacturer
PBE	public business entity
PBO	projected benefit obligation

Abbreviation	Description
PCAOB	Public Company Accounting Oversight Board
PCC	Private Company Council
PCD asset	purchased financial asset with credit deterioration
PP&E	property, plant, and equipment
PRV	priority review voucher
PTRS	probability of technical and regulatory success
Q&A	question and answer
R&D	research and development
R&E	research and experimentation
REMS	risk evaluation and mitigation strategy
ROI	return on investment
ROU	right of use
SAB	Staff Accounting Bulletin
SAC	subjective acceleration clause
SEC	Securities and Exchange Commission
SFC	specified foreign corporation
SIFMA	Securities Industry and Financial Markets Association
S&P 500	Standard & Poor's 500 Index
TD	Treasury Decision
TPA	AICPA Technical Practice Aid
TRG	transition resource group
UTB	unrecognized tax benefit
VIE	variable interest entity
VWAP	volume-weighted average daily market price