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Preventing Insider Trading at Biopharma Companies

WRITTEN BY

Scott R. Jones

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Between clinical trial results, open-label trials, licensing and collaboration discussions, and acquisition or sale talks, development and clinical-stage public biopharma companies and their insiders often possess material, nonpublic information. And since company equity usually makes up a large part of insiders' compensation, legal issues arise when insiders have access to such information and want to trade their equity. To complicate matters, market regulators are watching and will be quick to ask who knew what, when they knew it, and who traded whenever a company's stock price moves significantly. To protect against insider trading risks and regulatory scrutiny, it is key to have a robust control environment for insider trading.

Insider-Trading Policies

The cornerstone of a well-functioning control environment is a good insider-trading policy. This policy will provide directors, officers, employees and others with a clear statement of the rules for transacting in the company's securities. The existence of such a policy also may help insulate the company from the actions of the SEC and others should an employee or someone else engage in insider trading in violation of the policy.

There is no "one-size-fits-all" form for insider-trading policies; company size, industry, number of locations and other variables will dictate what should be included in a company's policy. But there are several topics that should be addressed in all policies.

Clearly State Who Is Covered

All directors, officers and employees should be covered by your insider-trading policy, but the policy should not stop there. It should also address consultants, family members of directors, officers and employees, investment clubs, and other ventures that directors, officers and employees may be involved with. In addition to addressing who must comply with the general provisions of the policy, when a policy calls for preclearance of trades, quarterly blackout periods or other conditions that may only be applicable to certain persons, the policy should define who those persons are (or how to identify them).

Say Which Transactions Are Covered

The treatment of all possible transactions by covered persons in your company equity, debt and derivative securities directly or indirectly (such as through a 401(k) or employee stock purchase plan) should be addressed (including the exercise or conversion of derivative securities, such as employee stock options).

Include Any Other Prohibited Activities

In addition to addressing trading activity, the policy should also prohibit “tipping” or sharing material, nonpublic information with someone else who then can trade in the company’s securities. Another common prohibited activity is trading in the securities of other companies where a person is in possession of material, nonpublic information about that company as a result of her affiliation with yours. Information sharing is common among collaboration partners, and your employees and others affiliated with your company should not be trading in the securities of a collaboration partner when they have material, nonpublic information about that partner.

Define Material, Nonpublic Information

Whether in the policy itself or by reference to another policy, what constitutes material, nonpublic information should be defined. While the policy should refer to a legal standard, such as “what a reasonable investor would consider to be important in deciding whether to transact in the company’s securities,” it should also include plain-English examples of the types of information material to your company’s business.

Establish Quarterly Blackout Periods

The policy should call for blackout periods (or prohibit trading) around each quarterly period end, as these are times when directors, officers and others are typically in possession of material, nonpublic information related to quarterly results. The beginning and end of these blackout periods should be defined in the policy. The blackout period should start no later than the date by which results are sufficiently known by persons subject to the blackout.

To be on the safe side, many companies start this blackout period a few days to up to two weeks ahead of a quarter’s end. If your company’s finance department does not start compiling results until after the end of the quarter, starting the blackout period on the last day of the quarter may be appropriate. As to the end of the blackout, it should be when results have been released and the markets have absorbed the information.

How long it takes the markets to absorb the information varies from company to company, depending on the nature of the market for a company’s securities, but one to three trading days is the generally accepted period. Most companies lift their quarterly blackout period on the first, second or third trading day after results are released.

Allow for Issue-Specific or Ad-Hoc Blackouts

While the quarterly blackout periods should be hardwired into the policy, the policy should also allow for the imposition of issue-specific or ad-hoc blackout periods. This is especially useful for biopharma companies that want to establish blackouts around such events as partnering discussions, the receipt and release of clinical data, etc. The compliance officer should have the authority to establish these blackouts and determine who should be subject to them.

Require Preclearance for Trades

Preclearing trades is one more control that will help prevent inappropriate trading by a company's employees. The preclearance procedures should apply at all times. During blackout periods, preclearance facilitates enforcement of a pending blackout period. During times when a blackout period is not in place, preclearance will allow the compliance officer to determine whether the person requesting the trade possesses material, nonpublic information that the compliance officer was not otherwise aware of (or may not have risen to the point where a blackout could have been put in place).

Provide for a Compliance Officer to Administer the Policy

This is typically the general counsel. In addition to administering the policy, the compliance officer should also have the authority to establish issue-specific blackouts, preclear trades and adjust who is subject to the policy or specific portions of the policy (for instance, trade preclearance). The compliance officer should also be the individual who employees can go to with questions.

While there may be other information that could be beneficial to include in a particular policy, the above features form a solid foundation of a well-functioning insider-trading policy.

Other Policies

A strong insider-trading policy works to protect against improper trading activity, but your control environment should be broader. It should address improper trading, as well as who gets what information and what they can do with it.

Material Information Policy

A material information policy governs the flow of material information in your organization, and dictates who has access to what information. Because the policy controls who has access, it keeps the population of people with access to sensitive information small, in turn reducing the number of people who could engage in improper trades.

Your compliance officer should not rely solely on the operation of a policy to determine whether a person possesses material, nonpublic information when preclearance is requested. Rather, he or she should still conduct a full inquiry into whether the person requesting preclearance possesses material, nonpublic information, using the policy as a tool to track how this information should have flowed throughout the organization.

Disclosure/Regulation FD Policy

A disclosure/regulation FD policy complements a material information policy because it indicates the company's rules regarding making information public. In general, the policy limits who can speak for the company and how the general public will be made aware of material information the company wants to share. It also dictates how inadvertent disclosures of material information will be handled. While this policy will not necessarily have a direct impact on insider-trading activity, it will lay out how information will be disseminated publicly, which will cleanse insiders who possessed the material information that was formerly not public.

Other Aspects of a Robust Control Environment

‘Tone at the Top’

Policies are only part of the equation. The “tone at the top” is just as important. Management should not only enforce the policies, but also act in a manner that exhibits their observance of the policies. Any policy violations should be addressed quickly and equitably. There should be no special treatment for management, directors or any other persons in terms of policy enforcement (even though particular persons may have differing responsibilities pursuant to the policies themselves).

Management must foster an environment conducive to open communication regarding company policies. Everyone subject to the policies should know which policies they are subject to, and feel comfortable asking questions and talking about situations not addressed in those policies. It is a good idea to send out periodic communications to employees — either reminding them to be aware of applicable policies generally, or highlighting particular critical points.

Your board and management should also review all policies on a regular basis (at least annually). This is especially important for development and clinical-stage biopharma companies. As these companies progress with the development of their products toward commercialization, the companies themselves likely will evolve at a rapid pace, adding personnel, functions, business units, etc.

Confidentiality Obligations

Everyone who may come in contact with material information is bound to your company by obligations of confidentiality. For employees and consultants, this should be a contractual obligation established by a nondisclosure or confidentiality agreement.

Directors may also be asked to sign a confidentiality agreement as part of their onboarding process, but one of their fiduciary duties is to preserve the confidentiality of the company’s information. Lawyers and accountants are bound by professional ethics rules, which require that they keep client information confidential.

While your policies will address how material information should be handled or prohibit certain actions with respect to material information (*e.g.*, tipping), confidentiality obligations are stronger than company policies because they are actual undertakings by the obligated person to keep company information confidential.

Encourage the Use of Rule 10b5-1 Plans

Equity is typically a large component of compensation for management at development and clinical-stage biopharma companies. Because the trading window is often closed for long periods of time at these companies, encouraging the use of Rule 10b5-1 plans allows management to monetize their equity compensation while still complying with insider-trading policies and practices. In essence, Rule 10b5-1 plans allow insiders to make the most of those limited instances in which they can actually trade, even though they may not want or need to conduct a trade right at that moment.

The initiation of a Rule 10b5-1 plan should be viewed as a trade with respect to your insider-trading policy. If someone cannot trade, then he or she should not be able to put a new plan in place or modify an existing trade. Because of this, when trading windows are open, remind your insiders about the ability to use Rule 10b5-1 plans, and that they should either consider open plans or put in new plans to match their liquidity needs.

Such a reminder is critical for calendar–year-end companies because, for many such companies, the timing of filing Form 10-K and the end of the first quarter creates a situation in which the year-end blackout period runs right into the blackout period for the first quarter. As a result, insiders who anticipate liquidating equity in order to meet their tax obligations may not be able to do so without using a Rule 10b5-1 plan. Reminding insiders ahead of the year-end blackout will allow them to rectify this situation and put a plan in place.

Conclusion

As insider-trading allegations continue to draw regulatory scrutiny and dominate the headlines, companies — especially development and clinical-stage public biopharma companies — must be proactive in establishing a control environment that addresses their employees' possession of material, nonpublic information. Drafting and implementing strong, clear insider-trading policies, which are supported by management, will help a company decrease its insider-trading risk and will put it in the best position to address regulators' inquiries into stock price fluctuations.

Scott R. Jones is a partner in Pepper Hamilton's Health Sciences Department, a team of 110 attorneys who collaborate across disciplines to solve complex legal challenges confronting clients throughout the health sciences spectrum. Mr. Jones concentrates his practice in securities, mergers and acquisitions, and private equity transactions.