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A Newsletter from Chicago Underwriting Group, Inc.
Underwriters of D & O and Professional Liability Insurance

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COMMENTS ON THE LIFE SCIENCE INDUSTRY

The FDA (Food & Drug Administration) approval process for pharmaceutical or biological products created by the life science industry is marked by three phases of clinical testing:

- **Phase I**: normally lasts a year and typically involves tests on a small number of persons who are healthy. Among the goals of this phase is to determine safety, dosage, tolerance, absorption, metabolism and excretion, with an emphasis on safety.
- **Phase II**: usually involves testing several hundred persons including a limited number with the target disease or disorder; this phase may last around two years. The primary goal is to determine effectiveness.
- **Phase III**: this may last three years and is performed upon the drug's target patients. The size of the groups tested should be large enough to provide statistically significant verification of the drug's effectiveness and identification of any adverse reactions from long-term use.

Companies can submit their proposed Phase III testing protocols to the FDA for a Special Protocol Assessment that evaluates the proposed testing to see if the tests are adequate to meet the appropriate scientific and regulatory requirements. FDA agreement to the protocols can reduce the chance of ultimate FDA rejection by virtue of an unsatisfactory testing process.

After a successful Phase III, the company can file a New Drug Application with the FDA seeking final approval, a process that can last an average of 18 to 24 months. Upon approval the company may start marketing and distribution of the drug for the approved indication.

Typically, when a company's product enters Phase III the risk of claims against the company's directors and officers increases. This is due to many factors, but all essentially predicated on the expectation that the company may finally be getting close to marketing its product and generating revenue. But the Phase II period is not without risk; for example, negotiation of pre-approval licensing to third parties which can lead to possible allegations of data manipulation and concealment.

During Phase II and especially Phase III, the company's executives, directors and employees, assisted by qualified counsel, should exercise care in the following areas:

1. **Public Announcements**:

   a) These should be scrutinized to make sure they sufficiently and accurately describe what has happened, and should include relevant and specific risk factors that identify forward-looking statements as such under the PSLRA "safe harbor" guidelines.

   b) One qualified person from the company should be responsible for reviewing and authorizing all written statements concerning the drug and the status of the approval process before such statements are released.

   c) Executives who make oral presentations should be given precise, scripted language. If asked about anything not covered by that language the presenter should avoid off-the-cuff remarks, following up after the company has had a chance to study the question. In doing this, however, the company must guard against "selective disclosure" where information is released on a selective basis rather than disseminated generally.

If other credible sources provide inaccurate facts about the company and its product, the company may consider issuing a correcting statement. Securities laws do not generally require such corrections, but as a practical matter it may be prudent.

2. **Selling of Company Stock by Insiders**:

The company should be aware that trading of stock by insiders will be under greater scrutiny once the product is in Phase II or Phase III, and a material announcement regarding certain trial results or findings can have a significant impact on the stock price. Especially critical - and to be avoided - is insider trading that occurs based on trial results or information received from the FDA, as well as from any scientific advisory panels or independent monitoring boards, before the information is made public.

The corporate policy on insider stock sales should be amended to reflect the heightened exposure. This may include instituting or expanding "black-out periods" during which no insider trading is permitted. Company executives should consider implementing pre-arranged trading plans as permitted under SEC Rule 10b5-1; such plans can be prudent for insiders of any public company, but for the life science sector where stocks are typically more volatile these plans can be especially helpful.

Successfully passing through Phase III and receiving FDA approval does not end the need for vigilance. Drugs and treatments approved for marketing can still pose significant issues for the life science company that produced them. There is an FDA post-approval phase, Phase IV, during which the company must continue observation and evaluation of the drug's safety. The FDA also monitors use of approved drugs for conditions other than the approved medical indications. This practice is known as "off-label" use, and while doctors can prescribe FDA approved drugs for alternative uses, companies are not allowed to market their drugs for any such indications until the FDA has approved such use. It is important the company ensures its sales force does not market the product with this in mind.

There are considerable challenges posed by an industry sector where product development is measured in years, is scrutinized by investors, competitors, attorneys and regulators, yet if successful can produce enormous benefits to society and rewards for the risk-takers. ❖

Chicago Underwriting Group, Inc. has underwritten D&O for life science companies for over fifteen years.

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