Protect your patients and your assets

Fiore Healthcare Advisors provides independent safety leadership, system design, and management to ensure against surprises

http://www.fiorehealthcare.com
This public biotech firm lost ~90% of its value based upon a previously identified and fully labeled safety issue.

**WHY?**

- Merely observing and labeling a safety risk is **not** enough.
- Stakeholders need to understand the drivers of risk in order to make informed decisions.

The investment community reacts to **safety uncertainty** by simply walking away.

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In order to understand the impact of patient risk uncertainty, think like a physician:

Physicians frequently say:
“let’s try this and if it doesn’t work, we can try something else.”

Physicians rarely say:
“let’s try this and if you are harmed, we can try something else.”

Investors and payers alike are aware that doctors will not use a product with uncharacterized safety risks.
The Road to Recovery

- The road to recovery is long and expensive.
- Value lost due to safety related selloffs over hours or days requires months or years to recover.
- Credibility remains damaged for long periods of time.

Prescribers (and investors) can return under certain circumstances.

Uncertainty around transparency and liability leaves a cloud.

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The Relevant Question

How far should a biotech/pharma CEO go to identify and mitigate risk of significant safety issues?

The difference between what is known and what should be known is a matter of perspective, and the healthcare investment space sets a high standard for a biotech/pharma CEO.

Biotech/pharma leaders must:
- Prioritize patient safety
- Invest appropriately to identify potential safety issues.

Once an issue is uncovered, the firm must continue to:
- Investigate to understand and,
- Characterize the potential risk.
Portfolio thinking does not apply within a biotech/pharma company where a single safety issue has major impact:

- Patients deserve better
- A single event can destroy a company
- Deal economics often performance / milestone based
- Reputational risk is high
We are no longer surprised when:
Commercially oriented biotech/pharma leaders let safety responsibilities go unaddressed or leave them to a CRO, where incentives are misaligned.

We are surprised that:
Biotech/pharma boards and investors allow this behavior from their leaders.

Simple investments can:
• Help protect patients against potentially foreseeable issues
• Ensure preparedness to identify and address unforeseen issues quickly
• Decrease uncertainty around benefit/risk (major issue for payers and providers)
• Increase the credibility of the firm and leadership
Our staff of ex-Chief Medical Officers, former Heads of Safety, and Clinical Researchers will work to ensure the right balance of safety in an appropriate business context by understanding drivers for the firm and rolling up our sleeves to get work done.

### How FHA Can Help

<table>
<thead>
<tr>
<th>Independent, executive level safety leadership</th>
<th>Safety system review and rapid control</th>
<th>Optimization and maintenance until exit</th>
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<tbody>
<tr>
<td>✓ Senior level safety oversight is assigned to the project</td>
<td>✓ Review safety system against business strategy and needs</td>
<td>✓ Implement sustainable system and tools that is aligned with business strategy and ensures effectiveness and compliance</td>
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<td>✓ Interact with corporate management/board of directors</td>
<td>✓ Provide actionable recommendations for system elements such as resources, SOP, vendor controls, etc.</td>
<td>✓ Manage and execute the system, working alongside internal resources</td>
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<td>✓ Interact with health authorities</td>
<td>✓ Negotiate with vendors and partners to ensure all obligations are reasonable and met</td>
<td>✓ Transition along one of several paths when appropriate</td>
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<td>✓ Manage relationships with partners, investors, media, etc.</td>
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<td>✓ Interact with investigators</td>
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