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The Case of the Faulty Facility: Investigative Reporting on SFBC

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In November 2005, Bloomberg Markets magazine published "Big Pharma's Shameful Secret," an expose of the clinical trial industry.[1] The article is harshly critical of the industry's human protections practices. It focuses on SFBC's Miami Phase I research center. After publication of the story, SFBC's stock plunged, its two top executives resigned, it closed the research center, it moved its headquarters from Miami to other company facilities in New Jersey, and it renamed itself PharmaNet Development Group.

In September 2006, Public Broadcasting System (PBS) stations broadcast "A Bitter Pill," a show about the making of the expose. PBS station WNET of New York, producer of the show, leaves little to the imagination in its press release: "America's Investigative Reports Presents An Expose of Corrupt Profiteering and Grievous Disregard for Human Test Subjects in the Pharmaceutical Industry." The show is part of a series that celebrates investigative journalism.

The Bloomberg reporters appear to have found serious and blatant problems at the SFBC research center, perhaps the largest Phase I research center in the world. The story asks a legitimate question: How did these problems persist under the eyes of the FDA, several IRBs, and SFBC's numerous customers?

The story is not entirely negative; it also recommends constructive steps such as creating a national registry of clinical research subjects and their study-related injuries. Privacy is obviously an issue, but such a registry would largely prevent people from participating in multiple clinical trials at the same time. It would also give research sites, IRBs, pharmaceutical companies, and the public useful information about the risks of experimental drugs.

It is standard practice for investigative journalists to attack their targets for any falsehood or deception. The Bloomberg story and WNET television show are no exceptions. One might, therefore, expect the journalists to hold themselves to a high standard of accuracy. Ronald Henkoff, Editor of Bloomberg Markets apparently agrees. In the WNET show, he states:

> "I tell reporters, no matter what the story is, I say there are a million facts in this story and they all have to be right. And in this kind of story, there are maybe two million facts and they all have to be right because you know its going to be contentious, you know its going to be controversial. You don't want anybody to attack you even on the smallest, seemingly inconsequential fact."

Did the Bloomberg story and the PBS show comply with this extremely high standard of accuracy? Or, did they display the same dishonesty of which they accuse SFBC and their other targets?

It is beyond the scope of this article to investigate every statement in the WNET show and Bloomberg article. Even with subpoena powers and unlimited resources, it may not be possible to determine the complete truth. However, the following statements of fact appear to be questionable:

Statements in "A Bitter Pill"

1. "And human trials always come with risks." (Sylvia Chase, narrator and investigative journalist)

   Deceptive. Strictly speaking, clinical trials always come with risks, although the risks may be no higher than those experienced in normal everyday life. For example, Phase IV trials may compare widely-used drugs with strong safety records. Or, the risks may be lower. For example, if a clinical trial compares a new treatment for a fatal disease with an ineffective standard-of-care treatment, the risk of participating may be far lower than the risk of not participating.

2. "They [SFBC] would inject him with massive amounts of this drug [in a trial of a "muscle-regeneration" drug]." (Mike Smith, Bloomberg Markets Senior Writer)

   Probably false. Mr. Smith probably had no information about the amount of drug administered to this specific subject. If he did, he probably did not obtain a scientific evaluation of the dosages.

3. "When you go to these clinical trials and [sic] there's no one there looking out for the safety of the patients." (Jonathan Neumann, Bloomberg Markets Senior Editor)

   False. Based on the context of Mr. Neumann's statement, he was referring to all clinical trials, not just those conducted by SFBC. The system at SFBC may have been defective, but the Bloomberg story, despite interviews with "dozens" of subjects and "non-stop" investigative work over "the better part of a year," says nothing to the effect that any subject was ever injured. This statement is clearly false about clinical research in general.

4. "You cannot rely on the inspection process to get quality into the system." (Joanne Rhoads, Director of FDA's Division of Scientific Investigations when the Bloomberg story was published)

   Deceptive. Inspection systems are not intended "to get quality into" any system. They are designed to confirm that other quality measures are effective. According to modern management theory, you cannot inspect quality into a product; you have build it in.

5. "The [FDA doesn't] even know how many [private IRBs] there are out there." (David Evans, Bloomberg Markets Senior Writer)

   Deceptive. There are only about 35 to 40 commercial IRBs in the United States and Canada. The WNET show favors IRBs affiliated with institutions; the challenge is counting those IRBs, of which there are thousands.

6. "The oversight is nonexistent" (Liz Willen, Senior Writer, Bloomberg Markets)

   False. This statement ignores the FDA's Bioresearch Monitoring Program (BIMO) and New Drug Application (NDA) review groups, thousands of IRBs, and tens-of-thousands of site monitors employed by pharmaceutical companies.

7. "...Food and Drug Administration, which, as documented in the reporting, had essentially stopped enforcing rules governing human clinical trials years ago." (Sylvia Chase, narrator and investigative journalist)

   Probably false. For the statement to be true, the FDA's level of enforcement must have declined by a very large percentage, which is probably not the case, assuming it declined at all. The Bloomberg story provides a counter-example: The FDA began, in January 2005, the process to shut down Fabre Research Clinic.

8. "We slept about seven to eight people to a room." (Marlon, study subject)

   Probably false. This statement contradicts the Bloomberg story, which says that "participants sleep six to a room in double-decker beds." The Bloomberg story probably would have included this statement if the reporters considered it true.

Statements in "Big Pharma's Shameful Secret"

The three Bloomberg reporters "spent an entire day… on the phone going through the entire 13,000-some-odd-word story, reading every sentence, and asking ourselves 'how do we know that this is true?'" Nevertheless, the Bloomberg article includes some form of most of the above statements. The article also makes the following statements:

9. "Now, more than 75 percent of all clinical trials paid for by pharmaceutical companies are done in private test centers or doctor' offices, according to CenterWatch… The centers – there are about 15,000 in the U.S. – sometimes have incomplete or illegible records."

   Partly false and partly deceptive. The "centers" – "private test centers" – number in the dozens or, at most, the low hundreds. There may be a combined total of about 15,000 private test centers AND doctor's offices where clinical trials are conducted. There is no evidence that private test centers have a bigger problem with incomplete or illegible records than any other type of site. As a whole, they may have a smaller problem because, in general, they are run in a business-like manner.

10. "For the Johns Hopkins review, WIRB's nine-member panels often met with just five members present, the minutes show. Alternative members made up the majority of WIRB boards 20 times from Jan. 1, 2004 to March 31, 2004. Twice in three months, all of the members were alternates."

    Deceptive. IRB boards include alternate members to ensure that meeting attendance satisfies the regulatory requirement of five members. The status of an IRB member as an alternate does not imply that he/she is inferior to a regular member.

11. "That's just what you fear from commercial IRBs. They've had conflicts of interest since the beginning."

    Deceptive. Because clinical trial sponsors pay commercial IRBs to review their studies, the IRBs clearly have a conflict of interest. However, the conflicts may be greater at IRBs affiliated with research institutions: Research institutions rely on revenue from industry-sponsored clinical trials to support their research programs. IRB members and investigators may have complex relationships in their academic, administrative and other roles that present multiple conflicts of interest.

Responses

A manuscript of this article was provided for comment to Bloomberg Markets, WNET and PharmaNet Development Group. 21 hours later, one response, from Bloomberg Markets, was received:

> Good morning. This is in response to your communication with Bloomberg Markets regarding allegations you plan to publish in an attempt to discredit the Bloomberg Markets investigative story on clinical trials. Upon review of your proposed

statements, we believe that they are completely unfounded. We stand by our story. Thank you for checking. Judith Czelusniak, Bloomberg L.P. [spokesperson]

Ms. Czelusniak's response efficiently expresses defensiveness, stonewalling and insincerity, delicately sidestepping substance. It appears that Bloomberg Markets would rather be asking the questions.

In the WNET show, Mike Smith, Bloomberg Markets Senior Writer, stated "SFBC was not claiming formally to us that there was anything inaccurate in the story. They said all this to their investors, but they never demanded a correction of anything factually wrong." Based on the response – or lack thereof – above, perhaps Mr. Smith's comment was a bit disingenuous.

Conclusion

The Bloomberg story and WNET show appear to identify serious problems that SFBC, its customers and IRBs, and regulatory authorities should have addressed before Bloomberg reporters knocked on SFBC's door. Bloomberg's Mr. Henkoff is absolutely correct when he says that "You don't want anybody to attack you even on the smallest, seemingly inconsequential fact." Unfortunately, erroneous and deceptive statements in the Bloomberg story and WNET show compromise their credibility and make it easy to dismiss them entirely as biased and defective, thereby diminishing a valuable learning opportunity. Were any of the apparent inaccuracies and deceptions worth the sacrifice of journalistic integrity? It is a shame that the Bloomberg and WNET reporters apparently hold themselves to lower standards than they hold their targets.

Reference

1. "Big Pharma's Shameful Secret", David Evans, Michael Smith, and Liz Willen, Bloomberg Markets, last accessed 9/30/06 at http://www.bloomberg.com/specialreport/pharma.pdf

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