UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF PENNSYLVANIA

[redacted] Individually and on Behalf of All Others Similarly Situated, Plaintiff, vs. HEMISPHERX BIOPHARMA, INC. and WILLIAM A. CARTER, Defendants.	Civ. Action No. CLASS ACTION COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS DEMAND FOR JURY TRIAL

INTRODUCTION AND OVERVIEW

1. This is a class action for violations of the anti-fraud provisions of the federal securities laws on behalf of all purchasers of securities of Hemispherx Biopharma, Inc. ("Hemispherx" or the "Company") between February 18, 2009 and October 30, 2009 (the "Class Period"), who were damaged thereby (the "Class").

2. Hemispherx is a biopharmaceutical company engaged in the clinical development, manufacture, marketing and distribution of new drug therapies based on natural immune system enhancing technologies for the treatment of viral and immune-based chronic disorders. The Company's products include Ampligen, an experimental drug undergoing clinical development for the treatment of chronic fatigue syndrome. The Company is headquartered in Philadelphia, Pennsylvania.

3. During the Class Period, defendants misled investors regarding the status of Hemispherx's New Drug Application ("NDA") for Ampligen with the U.S. Food and Drug Administration ("FDA"). Specifically, defendants failed to disclose that the FDA had requested several reports from the Company before the NDA could even be considered, thus delaying the possible approval of Ampligen by several months at a minimum.

4. On November 2, 2009, the Company issued a press release entitled "Hemispherx Biopharma Updates Chronic Fatigue Syndrome (CFS); Treatment and Commercial Application Programs; Targets Completion of All NDA Regulatory Responses and Initiation of Expanded Clinical Collaborations in CFS." The release stated in part:

> The Company also plans to complete all outstanding queries from the FDA regarding its New Drug Application (NDA) for Ampligen®, an experimental therapeutic, during November and December, 2009. On May 26, 2009, the Company announced a delay on the Ampligen NDA which, at the time, had a PDUFA date of May 25, 2009. As noted in the 10-Q and 10-K filings at the time, the FDA did not request additional information from the Company at that time. However, several outstanding NDA items, requiring Hemispherx responses, existed at the time of the FDA delay as noted in the August 8, 2009, 10-Q filing. Between March 9, 2009 and

September 15, 2009, the Company issued six (6) new reports to the Agency spanning various subjects including a) clinical safety assessments, b) specialized pre-clinical toxicology reports, and c) abbreviated chemistry and manufacturing control reports. The Company believes that these reports may fully retire all Agency queries in these particular areas.

The Company also plans to submit four (4) additional reports on interrelated topics in November and December, 2009, which will include pharmacokinetic analyses in multiple lower animal species (primates, rodents, etc.) ("the Lovelace Laboratory Studies") and final validation reports of certain manufacturing procedures conducted at an independent facility, Hollister-Stier Laboratories in Spokane, WA. Some of these reports were recently cited in BioMedReports.com and the Science Business Exchange (October 15, 2009).

5. As a result of this disclosure, the price of Hemispherx's securities dropped from $1.45 on the previous trading day to close at $1.13 on November 3, 2009, a drop of more than 20%. This decrease was a result of the artificial inflation caused by defendants' misleading statements coming out of the price.

JURISDICTION AND VENUE

6. The claims asserted arise under §§10(b) and 20(a) of the Securities Exchange Act of 1934 ("1934 Act") and Rule 10b-5. Jurisdiction is conferred by §27 of the 1934 Act. Venue is proper pursuant to §27 of the 1934 Act. Hemispherx's headquarters are located in Philadelphia, Pennsylvania and false statements were made in this District and acts giving rise to the violations complained of occurred in this District.

THE PARTIES

7. Plaintiff [redacted] purchased Hemispherx securities during the Class Period as set forth in the attached certification and was damaged thereby.

8. Defendant Hemispherx is a biopharmaceutical company with its headquarters located in Philadelphia, Pennsylvania. Hemispherx's securities are traded under the symbol HEB on the AMEX, which is an efficient market.

9. Defendant William A. Carter, M.D. ("Carter") was, at all relevant times, Chairman of the Board, Chief Executive Office ("CEO") and a director of the Company.

SCIENTER

10. During the Class Period, the defendants had both the motive and opportunity to conduct fraud. They also had actual knowledge of the misleading nature of the statements they made or acted in reckless disregard of the true information known to them at the time. In so doing, the defendants participated in a scheme to defraud and committed acts, practices and participated in a course of business that operated as a fraud or deceit on purchasers of Hemispherx securities during the Class Period.

PRE-CLASS PERIOD EVENTS

11. On July 7, 2008, the FDA accepted Hermispherx's NDA for Ampligen, which was originally filed in October of 2007. According to defendants, a response from the FDA was expected by February 25, 2009.

FALSE AND MISLEADING STATEMENTS DURING THE CLASS PERIOD

12. On February 18, 2009, the Company issued a press release entitled "FDA Extends Hemispherx's NDA Review Date for Ampligen® as Potential Treatment for CFS," which stated in part:

> Hemispherx Biopharma, Inc. has received a letter from the Food and Drug Agency ("FDA") indicating that the originally scheduled Prescription Drug User Fee Act ("PDUFA") date on the Ampligen® (Poly I:Poly C12U) New Drug Application (NDA) would be extended by three months "in order to provide time for a full review of the submission." Additional data were received by the FDA within 3 months of the user fee goal date.
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> Due to constraints at the FDA, specifically and including the increased workload related to the recently enacted and implemented FDA Amendments Act ("FDAAA") and FDA's Safety First/Safe Use initiatives, work priorities may change resulting in the Agency going past the customary PDUFA goal set for reviews of an application.
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> A decision was originally expected by February 25, 2009, for the Company's submission of its Ampligen® NDA . . . . The extended user fee goal date is now May 25th, 2009.

Extensions of NDA reviews are a separate category of FDA response, distinct from a complete response letter or approval by the PDUFA date, and have always existed. Prior to the recent new FDA initiatives (cited above) and resultant increased workload, "on time" action by the Agency has generally ranged between 68 and 100 percent for the standard NDA reviews between FY 1999 and FY 2006.

13. On March 13, 2009, the Company filed a Form 10-K with the Securities and Exchange Commission ("SEC") for the fiscal year ending December 31, 2008, which stated in part:

> On July 7, 2008 we were notified that the FDA had accepted for review our amended NDA filing for using Ampligen® to treat CFS. FDA approval of this application would provide the first-ever treatment for CFS. At present, only supportive symptom-based care is available for CFS patients. While we are optimistic, there are no assurances that the NDA will be approved. Over the summer of 2008, our clinical monitors visited our sites associated with our AMP-511 cost recovery treatment program for the collection and audit of additional data to be submitted to the FDA in support of our NDA for CFS currently under review. FDA inspections of several clinical sites did not result in the issuance of any "483" reports indicating lack of compliance with various regulations governing clinical trials.
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> The FDA conducted a field inspection at Hollister-Stier Laboratories in Spokane, Washington in mid-2008 (June 19 to July 2, 2008). The Ampligen® final fill operations are performed under contract with Hollister-Stier. The inspection resulted in a Form FDA 483 with two observations dealing with reviews and validations of process variability. We are working with Hollister-Stier to finalize specific actions.
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> On September 19, 2008, we executed an agreement with Lovelace Respiratory Research Institute in Albuquerque, New Mexico to perform certain animal toxic studies in support of our Ampligen® NDA. These studies were requested by the FDA and will be done in collaboration with the resources of the New Brunswick facility. We expect these studies to be complete in April 2009.
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> FDA Extends NDA Review Date For Ampligen®
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> In February 2009, the Company received a letter from the Federal Drug Administration ("FDA") indicating that their originally scheduled Prescription Drug User Fee Act ("PDUFA") date on the Ampligen® (Poly I:Poly C12U) New Drug Application ("NDA") would be extended by three months "in order to provide time for a full review of the submission." A decision from the FDA was originally expected by February 25, 2009. The extended PDUFA date for Ampligen® is now scheduled for May 25, 2009. Due to constraints at the FDA, specifically and including the increased workload related to the recently enacted and implemented FDA Amendments Act and Safety First/Safe Use initiatives, work priorities may

change resulting in the agency going past the customary PDUFA goal date set for reviews of an NDA.

Extensions of NDA reviews are a separate category of FDA response, distinct from a complete response letter or approval by the PDUFA date, and have always existed. Prior to the recent new FDA initiatives (cited above) and resultant increased workload, "on time" action by the agency has generally ranged between 68 and 100 percent for the standard NDA reviews between fiscal years 1999 and 2006 (source: Annual FDA PDUFA Performance Reports (www.FDA.gov).

14. The Form 10-K was accompanied by a certification signed by defendant Carter, which stated:

I, William A. Carter, certify that:

1. I have reviewed this annual report on Form 10-K of Hemispherx Biopharma, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Registrant as of, and for, the periods presented in this report;

4. The Registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e))and internal control over financial reporting (as defined in Exchange Act Rules 13a-15 (f) and 15d-15(f)) for the Registrant and have:

a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c. Evaluated the effectiveness of the Registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d. Disclosed in this report any change in the Registrant's internal control over financial reporting that occurred during the Registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the Registrant's internal control over financial reporting; and

5. The Registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Registrant's auditors and the audit committee of the Registrant's board of directors (or persons performing the equivalent functions):

a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Registrant's ability to record, process, summarize and report financial information; and

b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the Registrant's internal control over financial reporting.

15. On March 19, 2009, on the Company's Q4 2008 earnings conference call, defendants made the following statements:

[Carter]: We believe that we have answered all the major questions that have been put forward with the Agency. Now under federal law, they can continue to ask questions as long as they want.

But we believe that the major questions which they have asked have in our opinion been retired. Obviously, we are trying to anticipate questions that might come up in the future so that we can be prepared should there be further questions.

Unidentified Participant: This May 26 that is going to come up?

[Carter]: ***Yes, May 25, we would expect definitive response letters at that point.***

16. On May 11, 2009, the Company issued a press release entitled "Hemispherx Biopharma Announces $18.3 Million Public Equity Offerings," which stated in part:

Hemispherx Biopharma announced today that it has agreed to sell up to $18.3 million in common stock and warrants in a registered offering to two institutional investors. The investors will purchase today, for $15 million cash, common shares of its stock at $1.10 per share.

17. Also on May 11, 2009, the Company filed a Form 10-Q with the SEC for the quarter ended March 31, 2009, which stated in part:

On July 7, 2008, the FDA accepted for review our NDA for Ampligen® to treat CFS, originally submitted in October 2007. We are seeking marketing approval

> for the first-ever treatment for CFS. At present, only supportive, symptom-based care is available for CFS patients. . . . . On February 18, 2009, we were notified by the FDA that the originally scheduled Prescription Drug User Fee Act date of February 25, 2009 has been extended to May 25, 2009.
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> The FDA conducted a field inspection at Hollister-Stier Laboratories in Spokane, Washington in mid-2008. The Ampligen® final fill operations are performed under contract with Hollister-Stier. The inspection resulted in a FDA Form 483 with two observations dealing with reviews and validations of process variability. We continue to work with Hollister-Stier to finalize specific actions to address the FDA Form 483 issues and Hollister-Stier has submitted a specific action plan to the Seattle, Washington office of the FDA.
>
> On September 19, 2008, we executed an agreement with Lovelace Respiratory Research Institute in Albuquerque, New Mexico to perform certain animal toxic studies in support of our Ampligen® NDA. These studies were requested by the FDA and will be done in collaboration with the resources of the New Brunswick facility. We expect these studies to be complete in mid-2009.

18. The Form 10-Q was accompanied by a certification signed by defendant Carter substantially identical to that quoted above.

19. On May 19, 2009, the Company issued a press release entitled "Hemispherx Biopharma Announces $16 Million Public Equity Offering," which stated in part:

> Hemispherx Biopharm announced today that it has agreed to sell up to $16 million in common stock and warrants in a registered offering to two institutional investors. The investors will purchase for $16 million cash, 11,906,976 common shares of its stock at $1.34375 per share.

20. On May 26, 2009, the Company issued a press release entitled "Hemispherx Biopharma Announces Possible Brief Delay in FDA Action on Ampligen® New Drug Application," which stated in part:

> Hemispherx Biopharma, Inc. today announced that the U.S. Food and Drug administration ("FDA") has advised the company that it may require up to 1-2 additional weeks to take action beyond the scheduled Prescription Drug User Fee Act action date of May 25, 2009 on the New Drug Application for Ampligen® (Poly I Poly C12U), a selective TLR3 modulator, for the management of Chronic Fatigue Syndrome. Reason for the possible delay was attributed by the Agency to certain staff scheduling changes which might (or might not) delay the report. Accordingly the Company's development plan for Ampligen® continues as described in the

recently filed 10Q and 10K, as the FDA did not request additional information from the Company at this time.

21. On June 12, 2009, on a *biomedreports.com* conference call, defendant Carter made the following statements:

> Interviewer: When the FDA makes a statement "one to two weeks" and then not following through in terms of rendering a decision, what recourse does the public, or even the company, have? How are you feeling about that?
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> [Carter]: . . . as a company we've put forward a data package that we believe is compelling and we believe may be complete, and we're simply going to wait for FDA response.

22. On July 22, 2009, on the Company's conference call with investors and analysts, defendant Carter made the following statements:

> Barry Welts: Yes, I was wondering if there's any foreshadowing or new news of the FDA approval of Ampligen?
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> [Carter]: I gave a brief status report at the introduction to this conference but we've not received any recent news from the agency and as I pointed out earlier in a call, we have a number of initiatives in the CFS area which are not dependent upon that specific set of correspondences from the agency. . . . In the past we've issued summary reports, now we're issuing complete auditive reports on a variety of safety issues that the agency has raised over several years. No new issues but now we're retiring them through – we believe we're retiring them more comprehensive reporting. So this is all going forward and as you know from earlier conference calls, we believe the agency is substantially overworked at the moment with its new initiatives. It has new senior management and we expect that sometime in the fall, perhaps sooner, we will be hearing from the agency.
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> Steve Gold: Hi Good Morning. Last we heard from the FDA there was a one or two week delay, I heard discussed ____ early in the beginning of the call. I want to get a little bit specific about that if I may. That was about two months ago or so. Next we heard you say that you're expecting, now expecting a response from them in the fall. What do you attribute this tremendous delay to? And to say that the agency is overworked or overloaded, wouldn't it be reasonable for the Company to request an update – an updated timeline from the FDA?
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> [Carter]: Well, the person to my knowledge who's done the most analytic work in this area is Dr. Cori Davis, an analyst at VexRider. And he reported several months ago that the agency was missing its _____ dates – I think he said around 60-65% of the time. So this is a common phenomenon with respect to the agency. And even though it is hiring several thousand new people under its recent Congressional

appropriation, it's going to take a while to train them. I don't want to suggest, and if I've suggested, that we're not in correspondence with the agency, that would be incorrect. We are regularly providing reports to the agency to different reviewers in different areas. For example, in the area of pre-clinical toxicology. And, so we are in correspondence with respect to the question of the definitive answer to our pending NDA. It's been our impression and that of our regulatory counsel that the agency knows that we are most eager to determine what their deliberations are. They were present at a meeting at the end of May as a member of the HHS committee on what's called Chronic Fatigue Syndrome Advisory Committee.gov. It was a two-day meeting. A number of presentations from patient groups about Ampligen. The FDA heard the presentations. The Center for Disease Control and Dr. Reeves made repeated reference to Ampligen as the therapeutic that he wished to study at the CDC. We've like to believe that that would be in a phase 4 post-marketing study. So the FDA is aware of the advocacy groups by virtue of their attendance at the CFS Advisory Committee meeting on Constitution Avenue and we feel that the appropriate course of action is to be responsive to any queries, shall we say, that are still out there. And that's what we've been doing, as I said, providing definitive documents where before there were summary documents which we felt retired the issue but was not necessarily the totally enriched document with schedules of numbers, etc., etc. So we're doing that. And we think that in their time the agency will respond and we have optimism about the ultimate conclusion. I mean we also know this is, unlike seasonal flu, this is a path which has not been tread by any manufacturer. That's something the agency has to consider and this is a new molecular entity. It's been 92,000 injections but that's not a million injections. So there's a safety consideration among many other things that the agency would be considering. We think it's best to leave them to their deliberations, work on all these ancillary issues, and invite them obviously to respond when they need any of the initiatives that we have.

* * *

Steve Gold: One final question is: Is the FDA currently awaiting any data or documents from Hemispherx that may be delaying this approval?

[Carter]: We don't think that there are any documents. It's always hard to understand materiality, but there were many, for example, many inspections done all over the country. The clinical site inspections, so far as I remember, were perfect. There were no so-called 483s, there were 483s – a small one issued on New Brunswick and a larger one issued on our contract fill and finish group in Ohio. The 483 into our facility, we retired we believe back to the best of our satisfaction roughly a month or six weeks ago. But we haven't yet received a response from the agency on that. But that's not unusual for them simply to accept a response and if they deem, if they still have a question, they may inspect again. We haven't heard that they will. We commented that on an earlier inspection that with respect to Holister Steer, there were so limited questions with respect to what's called mix and hold. That is, is the product being distributed in these very large tanks. We are still working on that. That's very common among perineal manufacturers to perfect that and shall we say the post-approval inspection. What we've done so far are pre-approval inspections. But there's still experiments that would necessarily have to be

done in the post-approval and some of those we're, shall we say, jumping the gun and doing them now in the hope that that will save time. Obviously Holister Steer has an excellent reputation in this field and we think that ultimately that will carry the day. Though I would say that as of today we don't have evidence, written evidence from the agency about the Holister Steer activity. We think that it will, as they've done many times in the past, be satisfactory to the regional office in Seattle which in turn will report that to the home office in Silver Spring, Maryland.

23. On August 10, 2009, the Company filed a Form 10-Q with the SEC for the quarter ended June 30, 2009, which stated in part:

On February 18, 2009, we were notified by the FDA that the originally scheduled Prescription Drug User Fee Act ("PDUFA") date of February 25, 2009 has been extended to May 25, 2009. On May 22, 2009, we were notified by the FDA that it may require up to one to two additional weeks to take action beyond the scheduled PDUFA action date of May 25, 2009. Since that date, no further notification has been received from the FDA.

* * *

The FDA conducted a field inspection at Hollister-Stier Laboratories in Spokane, Washington in mid-2008. The Ampligen® final fill operations are performed under contract with Hollister-Stier. The inspection resulted in a FDA Form 483 with two observations dealing with reviews and validations of process variability. We continue to work with Hollister-Stier to finalize specific actions to address the FDA Form 483 issues and Hollister-Stier has submitted a specific action plan to the Seattle, Washington office of the FDA. It is our expectation that these issues will be resolved and we will be able to complete the resultant sequential validations by the end of 2009.

On September 19, 2008, we executed an agreement with Lovelace Respiratory Research Institute in Albuquerque, New Mexico to perform certain animal toxic studies in support of our Ampligen® NDA. These studies were requested by the FDA and will be done in collaboration with the resources of the New Brunswick facility. These studies have been substantially completed with summary reports expected to be issued to the FDA during the third quarter of 2009. Data for final FDA reports are presently undergoing internal auditing at Lovelace and Hemispherx with a projected completion of the final report for late 2009 to early 2010.

24. The Form 10-Q was accompanied by a certification signed by defendant Carter substantially identical to that quoted above.

25. On September 9, 2009, at the Rodman & Renshaw Global Investment Conference, defendant Carter made the following statements:

Now, we have a pending FDA approval we expected to hear. ***We have a complete application***. We've been answering questions for about a year. We expected to hear in late May. We have not yet heard. Different speculations as to why we haven't heard on that application. Obviously, we don't know what would be the reason for the apparent slowdown, but we do know that about 50% of the time with the incremental workload that the FDA is not meeting so-called PDUFA dates.

* * *

[Question]: Do you think before the last time you had any contact with the FDA regarding the Ampligen application?

[Carter]: We – I would say, yesterday, we provided in Annual Report on both of these products yesterday, annual reports basically look at the clinical activity, any adverse events.

[Question]: But when did you have an actual conversation with someone at the FDA. You obviously updated that they are reviewing Ampligen specifically. Did you – when was the last time you had a conversation, when you called them and said, hey, what's going on with the review?

[Carter]: We have not called them and asked that question. We do, I think, I might have described this in that recent conference call. We have regular interactions with reviewers providing documents. Essentially these have been documents in the pre-clinical safety issue. We forward documents. If they have questions, they send it back.

[Question]: So you have not – you've not – no one at Hemispherx has called FDA and said, we were suppose to hear from you on May 25, and it's now September 9. You never had – you never called them?

[Carter]: No, it's our belief that, a, in the good space of time, the FDA will respond to us much like they do to all other companies. And in the meantime, we are cleaning up to, so to speak, and this is obviously jargonize, certain open issues that are related to the pre-approval inspection of the drug.

26. On September 19, 2009, *TheStreet.com* published an article entitled "Hemispherx Hasn't Called FDA on Ampligen Review," which stated in part:

As the crowd [at the Rodman & Renshaw Global Investment Conference] was breaking up to make way for the next presenting company, I walked up to Carter, introduced myself, and asked him to more fully explain what he meant when he said the company was "cleaning up certain issues" with the FDA.

On numerous occasions since May, Carter has stated that the company wasn't aware of any deficiencies in the Ampligen data package and that the FDA hasn't asked the company for any additional information.

His answers to my question at the Rodman conference suggested a change to that stance. More specifically, I wanted Carter to explain why the company made a small but seemingly important alteration to the wording of its quarterly reports filed to the Securities and Exchange Commission.

Hemispherx is working with its contract manufacturer Hollister-Stier Laboratories to resolve two deficiencies in the Ampligen fill-finish process found by FDA inspectors working out of the agency's district office in Seattle.

In previous quarterly reports to the SEC, Hemispherx stated that it, along with Hollister-Stier, had "submitted a specific action plan" to address the manufacturing deficiencies – known as a 483 letter in FDA legal parlance – found by the FDA's inspectors.

Hemispherx added new language to this section of its most recent 10-Q filed on Aug. 7. It reads: "It is our expectation that these issues will be resolved and we will be able to complete the resultant sequential validations by the end of 2009."

This means that Hemispherx and its contract manufacturer are still working on the fixes to Ampligen's manufacturing. And if the validation work won't be done until the end of 2009, that means FDA won't have a chance to review and/or approve the Ampligen manufacturing changes until well into 2010.

The new disclosure found in Hemispherx's SEC filing doesn't jibe with Carter's previous statements in which he insisted that the FDA has not asked the company for any more information about Ampligen.

Clearly that's not true. The FDA asked Hemispherx for information about Ampligen's manufacturing and is now waiting for corrective actions to be taken.

The FDA does not approve drugs with unresolved manufacturing issues.

* * *

I asked Carter about the new disclosures in his company's SEC filings and whether or not the unresolved manufacturing problems with Ampligen were delaying the drug's approval.

"I don't know. I'm not sure," he said, in response. Then he added, "Perhaps it's because the commissioner's husband worked for a hedge fund."

By commissioner, Carter was referring to newly appointed FDA Commissioner Margaret Hamburg, whose husband, Peter Fitzhugh Brown, is an officer at the hedge fund Renaissance Technologies. Brown had to divest certain stock holdings in drug companies held by the hedge fund before Hamburg could take her post. According to Carter, Brown's fund owned a stake in Hemispherx.

I explained to Carter that the FDA commissioner doesn't actually review drugs. This is work done by the various divisions of the FDA and that Ampligen's review, including the inspection of its manufacturing facilities, wouldn't have

anything to do with whether or not Commissioner Hamburg's husband worked for a hedge fund or not.

"I have to go now. Let's get out of here," said Carter as he walked away.

27. On October 9, 2009, during an interview with *biomedreports.com*, defendant Carter made the following statements:

> Interviewer: We have been contacted by so many members of the investment community who have asked us to contact you in regards as to whether or not there has been communication between your Company and the FDA about the status of that drug application.
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> [Carter]: As I noted at some of the recent health care conference, we continue to be in contact with the agency concerning certain requests that they have made to us over the last year that have to do with what we call toxicology. This is non-clinical work on the drug which is customarily part of the new drug application. So we have continued to complete reports and we expect sometime this quarter, the fourth quarter, to complete a set of requirements which have to do with clinical toxicology – sorry, pre-clinical toxicology. Now, in addition to that, the agency has done a number of audits of our clinical sites as well as our manufacturing facility over the last 12 months. I'm very pleased to say that the clinical inspections resulted in no findings which required corrective action by the Company, which I believe is a very unusual positive result given the complexity and the duration of our clinical studies. However, the agency did note certain compliance issues at our facility in New Brunswick, which we own, and also at a contract laboratory in Spokane, Washington, where we do something called fill and finish. We put the Ampligen into the final container. Now over the summer of 2009 we remediated the small compliance issues that existed in our own facilities and we submitted to the regional office of the FDA which is in New Jersey. At the present time we are about to complete the remediation as we see it in the contract laboratory in Spokane. I believe in the next several weeks that will be complete and that will generate a report to the regional office of the agency which is in Seattle, I believe. Now until all those reports are completed and filed satisfactorily with the agency, the agency can withhold a final decision on the commercialization of the product. But we believe we will have achieved everything to the best of our knowledge which is necessary for a completion of pre-approval inspections by the agency. So we would expect at any time thereafter to receive final comments from the FDA. I might add that our studies, which are very tedious and require using independent laboratories which we've had in New Mexico and in Pennsylvania, we have not uncovered any information which was be deleterious to an approval of the product.
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> Interviewer: In one of the recent 10-Q's we find that in September 2008 you executed an agreement with Lovelace Respiratory Research Institute in New Mexico to perform certain animal toxic studies in support of that new drug application, and that these studies were requested by the FDA to be done in collaboration with the resources of your New Brunswick facility. These studies have been completed with summary reports that are presently undergoing auditing at Lovelace and are expected

to be completed late 2009 or early 2010. It sounds like a check list that the FDA is going through in order to give you an approval or a decision on the approval. Is that accurate?

[Carter]: I think that's an accurate summary.

28. On October 9, 2009, *TheStreet.com* published an article entitled "Hemispherx CEO Carter Speaks: BioBuzz," which stated in part:

Some thoughts on the interview with Hemispherx Biopharma CEO Bill Carter that was posted online this morning:

* * *

- Carter acknowledged unresolved FDA "compliance issues" regarding Ampligen manufacturing at its New Jersey facility and a contract fill-finish plant in Spokane, Wash.

* * *

"Now until all those [manufacturing issues] are completed and filed satisfactorily with the agency . . . the agency can withhold a final decision on the commercialization of the product [Ampligen]. But we believe we will have achieved what we all pre-approval inspection by the agency so we would expect any time thereafter to receive final comments from the FDA.

DEFENDANTS' STATEMENTS WERE FALSE AND MISLEADING

29. During the Class Period, defendants misled investors regarding the status of Hemispherx's NDA for Ampligen with the FDA. Specifically, defendants failed to disclose that the FDA had requested several reports from the Company before the NDA could even be considered, thus delaying the possible approval of Ampligen by several months at a minimum.

THE TRUTH BEGINS TO COME TO LIGHT

30. On November 2, 2009, the Company issued a press release entitled "Hemispherx Biopharma Updates Chronic Fatigue Syndrome (CFS); Treatment and Commercial Application Programs; Targets Completion of All NDA Regulatory Responses and Initiation of Expanded Clinical Collaborations in CFS." The release stated in part:

The Company also plans to complete all outstanding queries from the FDA regarding its New Drug Application (NDA) for Ampligen®, an experimental

therapeutic, during November and December, 2009. On May 26, 2009, the Company announced a delay on the Ampligen NDA which, at the time, had a PDUFA date of May 25, 2009. As noted in the 10-Q and 10-K filings at the time, the FDA did not request additional information from the Company at that time. However, several outstanding NDA items, requiring Hemispherx responses, existed at the time of the FDA delay as noted in the August 8, 2009, 10-Q filing. Between March 9, 2009 and September 15, 2009, the Company issued six (6) new reports to the Agency spanning various subjects including a) clinical safety assessments, b) specialized pre-clinical toxicology reports, and c) abbreviated chemistry and manufacturing control reports. The Company believes that these reports may fully retire all Agency queries in these particular areas.

The Company also plans to submit four (4) additional reports on interrelated topics in November and December, 2009, which will include pharmacokinetic analyses in multiple lower animal species (primates, rodents, etc.) ("the Lovelace Laboratory Studies") and final validation reports of certain manufacturing procedures conducted at an independent facility, Hollister-Stier Laboratories in Spokane, WA. Some of these reports were recently cited in BioMedReports.com and the Science Business Exchange (October 15, 2009).

31. As a result of this disclosure, the per share price of Hemispherx's securities dropped from $1.45 on the previous day to $1.13, a drop of more than 20%. This decrease was a result of the artificial inflation caused by defendants' misleading statements coming out of the price.

32. On November 3, 2009, *TheStreet.com* published an article entitled "Hemispherx Cops to Ampligen FDA Delay," which stated in part:

Hemispherx Biopharma issued an "update" to the regulatory status of its chronic fatigue syndrome drug Ampligen in which the company essentially admits that its prior public statements were false and misleading.

Monday's statement was likely crafted by Hemispherx's lawyers as a way to help CEO Bill Carter wiggle out of public statements he made in May and June claiming the Ampligen application to the U.S. Food and Drug Administration was to be complete. Carter insisted regulators weren't asking for any additional information on Ampligen.

Carter's made these statements both before and immediately after the FDA approval decision date for Ampligen on May 25, which came and went without any word from the agency. ***We now know that Carter's statements were demonstrably false. The FDA application for Ampligen was not complete because several items were outstanding, the company now states.*** These included FDA requests for data on Ampligen's safety both in humans and animals. The FDA also required additional information about Ampligen's manufacturing.

In its Monday update, Hemispherx said it is still compiling all the data requested by FDA and will not be done until December.

* * *

The discrepancy is particularly relevant because Carter's public statements helped boost Hemispherx's stock price during the spring and early summer months and benefited the company when it went to raise money from investors.

Between May and early June, Hemispherx's stock price rose about 600%, reaching a high of $3.75 on June 4. The company raised $18 million on May 11, and another $16 million on May 19, right before the FDA was supposedly going to issue its approval decision for Ampligen.

Hemispherx's stock price continues to slide as the Ampligen regulatory delay drags on. The stock closed Monday at $1.33, down 65% from the June 4 closing high. During the same time period, the Nasdaq Biotechnology Index is up 5%.

LOSS CAUSATION/ECONOMIC LOSS

33. During the Class Period, as detailed herein, defendants made false and misleading statements by means of concealment and obfuscation of critical clinical trial data and engaged in a scheme to deceive the market. This artificially inflated the price of Hemispherx's securities and operated as a fraud or deceit on the Class. Later, when defendants' prior misrepresentations and fraudulent conduct became apparent to the market, the price of Hemispherx's securities fell precipitously, as the prior artificial inflation came out of the price over time. As a result of their purchases of Hemispherx securities during the Class Period, plaintiff and other members of the Class suffered economic loss, *i.e.*, damages, under the federal securities laws.

NO SAFE HARBOR

34. Hemispherx's verbal "Safe Harbor" warnings accompanying its oral forward-looking statements ("FLS") issued during the Class Period were ineffective to shield those statements from liability.

35. The defendants are also liable for any false or misleading FLS pleaded because, at the time each FLS was made, the speaker knew the FLS was false or misleading and the FLS was authorized and/or approved by an executive officer of Hemispherx who knew that the FLS was false.

None of the historic or present tense statements made by defendants were assumptions underlying or relating to any plan, projection or statement of future economic performance, as they were not stated to be such assumptions underlying or relating to any projection or statement of future economic performance when made, nor were any of the projections or forecasts made by defendants expressly related to or stated to be dependent on those historic or present tense statements when made.

APPLICABILITY OF PRESUMPTION OF RELIANCE: FRAUD ON THE MARKET

36. Plaintiff will rely upon the presumption of reliance established by the fraud-on-the-market doctrine in that, among other things:

(a) Defendants made public misrepresentations or failed to disclose material facts during the Class Period;

(b) The omissions and misrepresentations were material;

(c) The Company's securities traded in an efficient market;

(d) The misrepresentations alleged would tend to induce a reasonable investor to misjudge the value of the Company's securities; and Plaintiff and other members of the Class purchased Hemispherx securities between the time defendants misrepresented or failed to disclose material facts and the time the true facts were disclosed, without knowledge of the misrepresented or omitted facts.

37. At all relevant times, the market for Hemispherx securities was efficient for the following reasons, among others:

(a) As a regulated issuer, Hemispherx filed periodic public reports with the SEC; and

(b) Hemispherx regularly communicated with public investors via established market communication mechanisms, including through regular disseminations of press releases on

the major news wire services and through other wide-ranging public disclosures, such as communications with the financial press, securities analysts and other similar reporting services.

CLASS ACTION ALLEGATIONS

38. Plaintiff brings this action as a class action pursuant to Rule 23 of the Federal Rules of Civil Procedure on behalf of all persons who purchased Hemispherx securities during the Class Period (the "Class"). Excluded from the Class are defendants, directors and officers of Hemispherx and their families and affiliates.

39. The members of the Class are so numerous that joinder of all members is impracticable. The disposition of their claims in a class action will provide substantial benefits to the parties and the Court. Hemispherx had more than 126 million shares outstanding, owned by thousands of persons.

40. There is a well-defined community of interest in the questions of law and fact involved in this case. Questions of law and fact common to the members of the Class which predominate over questions which may affect individual Class members include:

(a) Whether the 1934 Act was violated by defendants;

(b) Whether defendants omitted and/or misrepresented material facts;

(c) Whether defendants' statements omitted material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading;

(d) Whether defendants knew or recklessly disregarded that their statements were false and misleading;

(e) Whether the prices of Hemispherx securities were artificially inflated; and

(f) The extent of damage sustained by Class members and the appropriate measure of damages.

41. Plaintiff's claims are typical of those of the Class because plaintiff and the Class sustained damages from defendants' wrongful conduct.

42. Plaintiff will adequately protect the interests of the Class and has retained counsel who are experienced in class action securities litigation. Plaintiff has no interests which conflict with those of the Class.

43. A class action is superior to other available methods for the fair and efficient adjudication of this controversy.

COUNT I

For Violation of §10(b) of the 1934 Act and Rule 10b-5 Against All Defendants

44. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

45. During the Class Period, defendants disseminated or approved the false statements specified above, which they knew or recklessly disregarded were misleading in that they contained misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

46. Defendants violated §10(b) of the 1934 Act and Rule 10b-5 in that they:

(a) Employed devices, schemes, and artifices to defraud;

(b) Made untrue statements of material facts or omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; or

(c) Engaged in acts, practices, and a course of business that operated as a fraud or deceit upon plaintiff and others similarly situated in connection with their purchases of Hemispherx securities during the Class Period.

47. Plaintiff and the Class have suffered damages in that, in reliance on the integrity of the market, they paid artificially inflated prices for Hemispherx securities. Plaintiff and the Class would not have purchased Hemispherx securities at the prices they paid, or at all, if they had been aware that the market prices had been artificially and falsely inflated by defendants' misleading statements.

48. As a direct and proximate result of these defendants' wrongful conduct, plaintiff and the other members of the Class suffered damages in connection with their purchases of Hemispherx securities during the Class Period.

COUNT II

For Violation of §20(a) of the 1934 Act Against All Defendants

49. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

50. Defendant Carter acted as a control person of Hemispherx within the meaning of §20 of the 1934 Act. By virtue of his position and his power to control public statements about Hemispherx, defendant Carter had the power and ability to control the actions of Hemispherx and its employees. Hemispherx controlled defendant Carter and its other officers and employees. By reason of such conduct, defendants are liable pursuant to §20(a) of the 1934 Act.

PRAYER FOR RELIEF

WHEREFORE, plaintiff prays for judgment as follows:

A. Declaring this action to be a proper class action pursuant to Fed. R. Civ. P. 23;

B. Awarding plaintiff and the members of the Class damages and interest;

C. Awarding plaintiff's reasonable costs, including attorneys' fees; and

D. Awarding such equitable/injunctive or other relief as the Court may deem just and proper.

JURY DEMAND

Plaintiff demands a trial by jury.

DATED: November 10, 2009