

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION**

CARLO M. CROCE,	:	
	:	
Plaintiff,	:	Civil Action 2:17-cv-402
	:	
v.	:	Judge James L. Graham
	:	
THE NEW YORK TIMES COMPANY, <i>et al.</i> ,	:	Magistrate Judge Elizabeth A. Preston
	:	Deavers
Defendants.	:	

DECLARATION OF MATTHEW E. KELLEY

Under penalty of perjury, I, Matthew E. Kelley, hereby declare as follows:

1. I am an associate in the firm Levine Sullivan Koch & Schulz, LLP, and am admitted *pro hac vice* as counsel for Defendants in the above-captioned matter. I submit this Declaration in support of Defendants' Motion to Dismiss. The facts stated below are true of my own personal knowledge, and if called to testify, I could and would testify competently thereto.

2. Attached hereto as Exhibit A is a true and correct copy of a transcript, produced at my direction and under my supervision, of the recording of an interview with Defendant James Glanz by WOSU-FM that is the subject of Paragraphs 75 and 163-67 of the Complaint in this matter. A recording of the interview was posted on March 9, 2017, on the WOSU website at <http://radio.wosu.org/post/amid-ethics-concerns-ohio-state-stands-behind-researcher-carlo-croce>.

3. Attached hereto as Exhibit B is a true and correct copy of a printout of the article, *When does 'overlap' become plagiarism? Here's what PLOS ONE decided*, RETRACTION

WATCH (Sept. 16, 2016), available at: <http://retractionwatch.com/2016/09/16/when-does-overlap-become-plagiarism-heres-what-plos-one-decided/>.

4. Attached hereto as Exhibit C is a true and correct copy of an Order and its attachments filed in *United States ex. rel. Wu v. Thomas Jefferson Univ.*, No. 97-3396 (E.D. Pa. June 6, 2000).

5. Attached hereto as Exhibit D is a true and correct copy of a printout of the article, *Retractions 3 and 4 appear for researcher facing criminal probe; OSU co-author won't face inquiry*, RETRACTION WATCH (May 5, 2014), available at: <http://retractionwatch.com/2014/05/05/third-and-fourth-retractions-appear-for-cancer-researcher-fusco-facing-criminal-investigation/>.

6. Attached hereto as Exhibit E is a true and correct copy of the Complaint in *Croce v. Sanders*, 2:17-cv-00338-JLG (Ohio Ct. Comm. Pl. April 20, 2017).

I declare under penalty of perjury and the laws of the United States of America that the foregoing is true and correct.

DATED: July 10, 2017

/s/ Matthew E. Kelley

Matthew E. Kelley

Exhibit A

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**LEVINE SULLIVAN KOCH &
SCHULZ, LLP**
**Radio Interview with
New York Times Reporter,
James Glanz, and
Ohio State University President,
Michael Drake**

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[START RECORDING]

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STEVE: One of Ohio State University's most decorated researchers is facing some tough questions about the quality of his work. A New York Times article this week says Dr. Carlo Croce has been fending off a tide of allegations claiming data falsification and other scientific misconduct in his cancer research. Joining us now is one of the reporters who wrote the piece, James Glanz, thanks for your time sir.

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MR. JAMES GLANZ: A pleasure.

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STEVE: First of all we did reach out to Carlo Croce, he said he's in Italy for the remainder of the week and could chat when he gets back. Until then he referred us to a statement from a Columbus law firm. We'll get to that in just a minute. First, James Glanz, this is a very big question but what are the basic allegations against Dr. Croce?

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MR. GLANZ: Well, the allegations are that in the lab he oversees, and on papers on which he's a co-author, there are call them fabricated figures. They're duplications of data from

1 unrelated experiments used to prove a point in
2 another experiment. I think that's probably at
3 the center of things and then there's some other
4 ethics charges including plagiarism and
5 misappropriation of grant money and things like
6 that. But it's really the data manipulation
7 that's at the center of the allegations.

8 STEVE: And certainly a lot of very damning
9 allegations for a researcher. Croce has never
10 been penalized by Ohio State. OSU President
11 Michael Drake was asked about this very issue on
12 our air Thursday morning. He said, after the
13 Times raised questions about OSU's response to
14 the allegations they contacted several people
15 with, what Drake called, national reputations to
16 look into the allegations. Here's what he said.

17 MR. MICHAEL DRAKE: And all the things that
18 they found showed that we had done, that we had
19 followed, our policies were appropriate and we
20 had followed them appropriately. So that's the
21 part that we really focused on. I think that
22 the way it turned out to be like we expected it
23 would.

24 STEVE: So there's OSU President Michael

1 Drake standing behind the response to the
2 allegations against Dr. Croce. What's your
3 reaction to hearing Michael Drake say that?

4 MR. GLANZ: Yeah, I'm not surprised. I mean
5 I think what he's saying is he feels that Ohio
6 State's handling of each of the cases that came
7 up, and which we reported in the article, was
8 proper.

9 STEVE: But they did not discipline Dr.
10 Croce, correct? So that would imply that he did
11 not do anything that rose to the level of
12 discipline.

13 MR. GLANZ: Yeah, well, a second thing about
14 the piece is that you have a situation where
15 institutions like Ohio State face a lot of
16 conflict of interest issues when they're
17 investigating. Their own researchers, partly
18 because of the prestige that the researcher and
19 also because the researchers receiving a lot of
20 grant money.

21 STEVE: But he also says they have invested
22 much more in Dr. Croce's research than he had
23 helped earn for the university.

24 MR. GLANZ: Right, we were not able to

1 verify that, but that is what they told us,
2 that's all I know about that.

3 STEVE: The statement from the law firm
4 representing Dr. Croce reads, "It is true that
5 errors sometimes occur in the preparation of
6 figures for publication. Any mistakes with
7 figures were "honest errors". The Times article
8 seems to imply that these allegations are worse
9 than that, that's why they wrote the article,
10 right? Does Dr. Croce have a point? Could
11 these be explained by just normal academic
12 mistakes?

13 MR. GLANZ: Well, again, I'm citing my
14 sources here Steve.

15 STEVE: Sure.

16 MR. GLANZ: And the way it usually goes is
17 that when these experts, forensic experts, we
18 consulted look at an individual allegation,
19 they're able to determine that an image has been
20 manipulated. The scientific image has been
21 manipulated. And we, to our satisfaction,
22 contacted a lot of these experts, are satisfied
23 that in fact that occurred in many images in
24 papers co-authored by Dr. Croce.

1 Now the next level is intent, right. Did
2 they mean to do it? And in any particular case,
3 again, when you see something that looks like
4 it's been photo-shopped in and so on, you can't
5 determine intent just by looking at the image,
6 right. So what we found though was people who
7 looked at many of these cases, these are our
8 sources again, believed that it was very
9 unlikely that this couldn't have been sort of a
10 pattern. In other words, it was part of a
11 pattern.

12 STEVE: And we certainly will have Dr. Croce
13 on our program when he is available. James
14 Glanz, co-authored a piece in the New York Times
15 that raises questions about the quality of
16 research by Carlo Croce, a well-known cancer
17 researcher at Ohio State. James Glanz, thanks
18 again.

19 MR. GLANZ: My pleasure, thanks Steve.

20 [END RECORDING]

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C E R T I F I C A T E

The prior proceedings were transcribed from audio files and have been transcribed to the best of my ability. I further certify that I am not connected by blood, marriage or employment with any of the parties herein nor interested directly or indirectly in the matter transcribed.

Signature *Wanda Elin*

Date July 3, 2017

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Exhibit B

Retraction Watch

Tracking retractions as a window into the scientific process

When does “overlap” become plagiarism? Here’s what PLOS ONE decided

[with 12 comments](#)



Consider this: Fragments of a *PLOS ONE* paper overlap with pieces of other publications. The authors used them without credit and without quotation marks.

This sounds an awful lot like plagiarism — using *PLOS*’s [own standards](#), even. But the journal isn’t calling it plagiarism. They’ve labeled this an instance of “text overlap,” a spokesperson told us, based on the amount of material that the paper shares with others.

The last author — Carlo Croce, who has two retractions under his belt — denies that he plagiarized, and says that his university has cleared him of a plagiarism charge from an anonymous whistleblower.

PLOS fixed this case last year with a [correction notice](#) — not the common course of action for a case of confirmed plagiarism. Take a look at the notice for yourself:

After the publication of the article [[MiR-34a/c-Dependent PDGFR- \$\alpha\$ / \$\beta\$ Downregulation Inhibits Tumorigenesis and Enhances TRAIL-Induced Apoptosis in Lung Cancer](#)], it was noticed that fragments of text in this article overlap with that from previous publications. The overlap in the text relates to the Introduction, Results and Discussion sections, where sentences were reproduced without quotation marks. We would like to acknowledge this and include the relevant references. It should be noted that no concerns have been raised regarding the originality of the work reported in the article and that this has no bearing on the results and conclusions of the study.

In the Introduction section there is some overlap in text with that from the following publications:

McDermott U, Ames RY, Iafrate AJ, Maheswaran S, Stubbs H, Greninger P, et al. Ligand-dependent platelet-derived growth factor receptor (PDGFR)-alpha activation sensitizes rare lung cancer and sarcoma cells to PDGFR kinase inhibitors. *Cancer Res.* 2009 May 1;69(9):3937–46. doi: [10.1158/0008-5472.CAN-08-432](#)

Hermeking H. The miR-34 family in cancer and apoptosis. *Cell Death Differ.* 2010 Feb;17(2):193–9. doi: [10.1038/cdd.2009.56](#).

Raica M, and Cimpean AM. Platelet-Derived Growth Factor (PDGF)/PDGF Receptors (PDGFR) Axis as Target for Antitumor and Antiangiogenic Therapy. *Pharmaceuticals (Basel).* 2010 Mar; 3(3): 572–599. doi: [10.3390/ph3030572](#)

In the Results section there is some overlap in text with that from the following article:

Tanaka N, Toyooka S, Soh J, Kubo T, Yamamoto H, Maki Y, et al. Frequent methylation and oncogenic role of microRNA-34b/c in small-cell lung cancer. *Lung Cancer*. 2012 Apr;76(1):32–8. doi: [10.1016/j.lungcan.2011.10.002](https://doi.org/10.1016/j.lungcan.2011.10.002).

In the Discussion section there is some overlap in text with that from the following publications:

Zhang H, Bajraszewski N, Wu E, Wang H, Moseman AP, Dabora SL, Griffin JD, and Kwiatkowski DJ. PDGFRs are critical for PI3K/Akt activation and negatively regulated by mTOR. *J Clin Invest*. 2007 Mar;117(3):730-8. doi: [10.1172/JCI28984](https://doi.org/10.1172/JCI28984).

West KA, Castillo SS and Dennis PA. Activation of the PI3K/Akt pathway and chemotherapeutic resistance. *Drug Resist Updat*. 2002 Dec;5(6):234–48

The 2013 paper has been cited 40 times, according to [Thomson Reuters Web of Science](#).

We find the wording in this notice strange, so we asked a spokesperson for *PLOS ONE* why the journal isn't calling this plagiarism. He said:

The journal office was alerted to instances of overlap in the text of the article with that from other publications. Upon follow up with the authors and evaluation of the level of text overlap, the editors considered that the most appropriate step was to issue a Correction to make readers aware of the instances of overlap in text with the sources listed.

It's not clear exactly how much of the text appears to overlap with the other publications — the spokesperson told us “the overlap involved sentences.” In one example, here's what we believe is the sum total of the text shared by the *PLOS ONE* paper and the [Pharmaceuticals paper](#) mentioned in the notice:

All members of the PDGF family display potent angiogenic activity *in vivo*, and from this point of view, PDGF-B/PDGFR β axis was the most extensive evaluated.

Virginia Barbour, the Chair of the Committee on Publication Ethics, told us that in general “there is no numerical value that can easily be applied” as to how much overlap constitutes plagiarism, adding that she cannot comment on specific cases.

The paper's last author [Carlo Croce](#), a researcher at The Ohio State University (OSU), denies that he plagiarized. To boot, he told us that he's been cleared of a plagiarism charge (it's unclear if that relates to this paper or not):

Following an [anonymous] denunciation the University investigated the matter and found that there was no plagiarism whatsoever. Keep in mind that people...reading a paper may get some sentence impressed in their mind and then repeat it in a paper. That has to be avoided, but it might happen. If the paper is completely different, possibly on a different subject, with completely different data it would be very difficult to claim plagiarism.

We were unable to verify the claim that OSU cleared Croce of a plagiarism charge. The Research Integrity Officer at OSU declined to comment on whether Croce had been investigated, citing an OSU policy against disclosing that information.

To shift gears a little here: this is not Croce's first tangle with notices. He shares two retractions with [Alfredo Fusco](#), a cancer researcher in Italy who has been under criminal investigation for scientific misconduct. And many of Croce's papers [have been flagged on PubPeer](#) by commenters suggesting that there are issues with some of the figures.

One of those papers [questioned on PubPeer](#), “[Downregulation of p53-inducible microRNAs 192, 194, and 215 Impairs the p53/MDM2 Autoregulatory Loop in Multiple Myeloma Development](#),” was corrected

earlier last month by *Cancer Cell* over image problems. Here's [the notice](#):

During figure preparation for the original article, the image of the western blot showing MDM2 protein expression upon miR-194,192, 215, and scrambled sequence (Scr) treatments in the MM1s cell line was mistakenly replaced in Figure 4A with the image of the western blot showing MDM2 in NCI-H929 cells in the same figure panel. The correct corresponding image of the western blot showing MDM2 protein expression in MM1s is shown below in the corrected Figure 4A.

In addition, because multiple normalizations of the same set of samples were performed due to the use of phospho-antibodies, the authors inadvertently duplicated the Gadph image of MM1s in the total Akt image of NCI-H929 in the same panel. The results were not affected by this duplication. The corresponding total Akt and Gapdh images used for pAkt normalization for both RPMI-8226 and MM1s are now included in the corrected Figure 7A, shown below.

The authors apologize for these errors and any confusion that they may have caused.

The 2010 paper has been cited 197 times.

In 2014, [we reported on a letter](#) from OSU to pseudonymous whistleblower Clare Francis saying the university and the U.S. Office of Research Integrity had chosen not to investigate a few of Croce's papers in response to specific allegations Francis raised in 2013. The reasoning: the manuscripts were not generated at OSU, and no OSU employees had contributed to the figures in question.

Hat tip: David Sanders

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In "alfredo fusco"

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In "ferric fang"

Written by Shannon Palus

September 16th, 2016 at 12:30 pm

Posted in [alfredo fusco](#), [cancer biology](#), [cancer cell](#), [cell press](#), [duplication retractions](#), [freely available](#), [image manipulation](#), [molecular biology](#), [plagiarism](#), [plagiarism euphemisms](#), [plos](#), [plos one](#), [united states](#)

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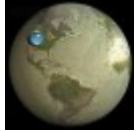


• Jaime A. Teixeira da Silva September 16, 2016 at 12:59 pm

PLOS ONE new EIC, Joerg Heber:

<http://blogs.plos.org/plos/2016/09/plos-appoints-dr-joerg-heber-editor-in-chief-of-plos-one/>

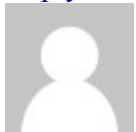
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• Tekija September 16, 2016 at 1:14 pm

I'd say, if one copies even the grammar errors – I think the example should read “extensively” (or perhaps “extensively one” depending on the intent, instead of “All members of the PDGF family display potent angiogenic activity in vivo, and from this point of view, PDGF-B/PDGFRβ axis was the most extensive evaluated.” – then I would not hesitate calling it plagiarism.

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• fernandopessoa September 16, 2016 at 1:30 pm

Cancer Cell. 2010 Oct 19;18(4):367-81. doi: 10.1016/j.ccr.2010.09.005.

Downregulation of p53-inducible microRNAs 192, 194, and 215 impairs the p53/MDM2 autoregulatory loop in multiple myeloma development.

Pichiorri F1, Suh SS, Rocci A, De Luca L, Taccioli C, Santhanam R, Zhou W, Benson DM Jr, Hofmainster C, Alder H, Garofalo M, Di Leva G, Volinia S, Lin HJ, Perrotti D, Kuehl M, Aqeilan RI, Palumbo A, Croce CM.

Author information

1Department of Molecular Virology, Comprehensive Cancer Center, Ohio State University, Columbus, 43210, USA.

<https://pubpeer.com/publications/20951946>

Not addressed by 2016 correction.

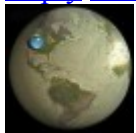
Figure 3E.

<http://i.imgur.com/1Z4W8a8.jpg>

Figure 5A.

<http://imgur.com/3alNrS2>

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• Tekija September 16, 2016 at 1:50 pm

Tekija

I'd say, if one copies even the grammar errors – I think the example should read “extensively”

(or perhaps “extensively one” depending on the intent, instead of “All members of the PDGF family display potent angiogenic activity in vivo, and from this point of view, PDGF-B/PDGFR β axis was the most extensive evaluated.” – then I would not hesitate calling it plagiarism.

“extensive one” (autocorrect, sorry)

[Reply](#) [Link](#) [Quote](#)



• K2 September 16, 2016 at 2:33 pm

Several related factors can make specific labs and networks susceptible to problems like plagiarism. When the first language in the lab is not the prevailing publication language (today, English). People who don't have a chance to practice their professional language in the professional setting are more likely to be tempted by shortcuts.

Lack of diversity. Related to language, why would any lab, in the US especially, be composed of senior people, postdocs and up, mostly coming from one foreign country?

Internal promotion. Most US universities encourage graduates and postdocs to move to other universities, but in some large labs, there appears to be a lot of internal hiring. This makes investigators highly interdependent and indebted to the bosses and sub-bosses, even if they ultimately leave for another university, and you might get more “honorary authorships” without proper scrutiny. There's also more tendency to circle the wagons when questions are asked.

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View 2 replies to K2's comment



• [Jeffrey Beall](#) September 16, 2016 at 4:24 pm

The question should be, “When does plagiarism become overlap?”. The answer is: When the author is paying to publish.

[Reply](#) [Link](#) [Quote](#)

View the reply to Jeffrey Beall's comment



• KK September 16, 2016 at 6:01 pm

Former editor-in-chief of premier journal – Cancer Research

<http://cancerres.aacrjournals.org/content/canres/57/16/local/ed-board.pdf>

[Reply](#) [Link](#) [Quote](#)



• Donald Osborne September 17, 2016 at 10:19 pm

“Text overlap” is equivalent to plagiarism if a paper is retracted. The more pleasant term is used to reduce the likelihood of a lawsuit, though meritless, but nevertheless a nuisance that journals would rather avoid.

[Reply](#) [Link](#) [Quote](#)



• *fernandopessoa* October 5, 2016 at 8:14 am

October 2016 Carlo Croce retraction.

<http://www.nature.com/nrclinonc/journal/vaop/ncurrent/full/nrclinonc.2016.163.html>

Nat. Rev. Clin. Oncol. (2016); published online: 26 July 2016; updated: 4 October 2016

I wish to retract the News & Views article ‘Are circRNAs involved in cancer pathogenesis?’ (Nat. Rev. Clin. Oncol. <http://dx.doi.org/10.1038/nrclinonc.2016.113>; 2016), owing to irreconcilable differences with the journal editors over correction of the text. Carlo M. Croce

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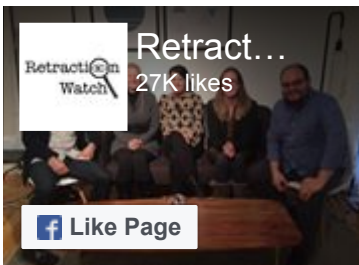
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The RW Daily: Duke admits fake data "potentially affected" grant apps; A biochemist's

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Exhibit C

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45

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA,
ex rel. YONG WU,

CIVIL ACTION NO. 97-3396

Plaintiffs,

v.

THOMAS JEFFERSON UNIVERSITY, et al.,

Defendants.

FILED

JUN - 6 2000

Michael J. ... Clerk
By _____ Dep. Clerk

ORDER

AND NOW, this ^{June} 6th day of ~~May~~, 2000, upon consideration of the foregoing Stipulation of Dismissal filed by the United States and Relator and after approval and entry of the Global Settlement Agreement and the Settlement Agreement by the Court,

IT IS HEREBY ORDERED:

The defendants are hereby dismissed from this action pursuant to and consistent with and subject to the terms of the Global Settlement Agreement and the Settlement Agreement executed by the parties. The Court shall retain jurisdiction for purposes of interpreting and enforcing the Global Settlement Agreement and Settlement Agreement.

Charles R. Weir

United States District Judge

ENTERED: _____

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TO: _____

Hoffman

6/7/00
[Signature]

X

GLOBAL SETTLEMENT AGREEMENT

I. PARTIES

This Global Settlement Agreement ("Agreement") is entered into by and between the United States of America, including the Office of Inspector General ("OIG-HHS") and the National Institutes of Health ("NIH") and the Office of Research Integrity ("ORI") of the Department of Health and Human Services ("HHS"), and the Deputy Assistant Secretary for Grants and Acquisition Management of HHS (collectively "United States") and Thomas Jefferson University ("TJU"), Carlo Croce, M.D. ("Croce"), and Jerold Glick ("Glick"), Yong Wu, M.D. ("Wu"), Lingxun Duan, M.D. ("Duan"), and Roger J. Pomerantz, M.D. ("Pomerantz") (hereinafter also referred to collectively as "the Parties"), through their authorized representatives.

II. PREAMBLE

As a preamble to this Agreement, the Parties agree to the following:

A. TJU is an educational institution located in Philadelphia, Pennsylvania which, among other items, receives federal funds for research purposes including federal grants from the NIH.

1. GRANT 55541

B. In August 1994, the Office of Management Assessment of the NIH commenced a management review of TJU's accounting practices that addressed: (1) TJU's policy and practices for allocating costs to National Cancer Institute ("NCI") funded projects; (2) the adequacy of TJU's time and effort reporting system to account for NCI funds on an individual project basis; and (3) alleged improper use of grant funds on a specific cancer research grant.

C. On or about August 12, 1996, NIH issued Management Report P-95-55 which addressed the findings made by the Office of Management Assessment. The Report found alleged deficiencies in several TJU management systems, including but not limited to, cost allocation and time and effort reporting. TJU responded to the findings by promptly implementing measures to address the alleged deficiencies. In addition, during the course of the management review, alleged improper activities relating to a specific federal cancer research grant were referred by NIH representatives to OIG-HHS for investigation. OIG-HHS Audit and Investigations conducted an investigation into alleged fraudulent activity associated with the grant. TJU conducted

its own internal investigation of the allegations and cooperated fully with the United States in the government's investigation.

D. As a result of the investigation, the United States contends that TJU, Croce, (the Chairman of TJU's Department of Microbiology-Immunology ("Department")), and Glick, (the former Senior Administrator for the Department), submitted or caused to be submitted false claims for payment to the NIH and the NCI for Grant R01 CA55541, "The Role of IGF1 in Cell Proliferation" ("Grant 55541").

E. The United States contends that it has certain civil claims against TJU, Croce and Glick under the False Claims Act, 31 U.S.C. §§ 3729-3733, other federal statutes and/or common law doctrines, for engaging in the following conduct during the period from March 1992 through October 1995:

(1) applying for federal grant funds for cancer research based upon false representations to the United States, i.e., the Principal Investigator (PI) for Grant 55541 had resigned and returned to Italy at the time of the grant award yet TJU, Croce and Glick confirmed his presence for purposes of obtaining the grant award; (2) failing to advise the United States of material changes in the status of researchers responsible for performing cancer research, i.e., the PI was, in

years 2 and 3 to spend 75% of his effort on Grant 55541 when, in fact, he was in Italy and was not performing the research; (3) charging of salaries to Grant 55541 for post-doctoral fellows who had nothing to do with that research; and (4) engaging in a pattern of false representations to the United States as a means of receiving federal research funds, i.e., TJU, Croce and Glick advised NCI that the PI was in the country performing research when he, in fact, was in Italy by executing or causing to be executed Applications for Continuation of Grant 55541 and Financial Status Reports relating to Grant 55541 which contained false or fraudulent information that were then submitted to the United States. From August 1992 through October 31, 1995, a total payment in the amount of \$496,000 was made to TJU by NCI for Grant 55541. The allegations described herein are referred to as the "Grant 55541 Covered Conduct".

(2) Additionally, once the alleged fraudulent activity was uncovered, an audit of 10 federally funded grants was agreed to by TJU and the United States. This audit was performed by Arthur Andersen LLP ("Andersen Audit"), and reviewed by the HHS, OIG-Audit, and addressed the administration and management of federal grants by TJU. The Andersen Audit of the 10 federal grants are identified as follows: 5 P01 AR38923-

09, 5 P01 AR38923-08, 5 P01 AR38923-07, 5 R01 AI33810-03, 5 R01 AI33810-02, 5-U01 AI32783-03, 5 R35 CA39860-12, 5 R35 CA39860-11, 5 P30 CA56036-02A4, 1 P30 CA56036-01A4, 5 P01 CA21124-17A3, 5 P01 CA21124-16A3, 3 P50 AA07186-11, 3 P50AA07186-10, 3 P50AA07186-09, 7 R01 CA51664-04, 5 R01 NS29857-06, 5 R01 NS29857-05, 5 HD7 TI00966-02. The results of the audit and the findings of the Andersen Audit were disclosed to the United States in a report of August 22, 1997, and correspondence of February 5, 1998 and February 13, 1998, providing additional information and clarification in response to questions, and are referred to herein as the "Anderson Audit".

F. The United States also contends that it has certain administrative claims and debarment actions against TJU, Croce and Glick under the provisions for eligibility to receive federal grants and contract funds, 45 C.F.R. Part 76 and 48 C.F.R. Part 9.4 for the Grant 55541 Covered Conduct.

G. TJU, Croce and Glick do not admit the contentions of the United States as set forth in Paragraphs D, E, and F, and deny any wrongdoing or liability with respect to the allegations against them. TJU contends that the absences of the PI for personal reasons, were reported to NIH and that the "science" which was contracted to be performed under Grant 55541 was

performed by qualified personnel at TJU, and that several publications demonstrate that the research provided pursuant to Grant 55541 has been utilized in furtherance of other scientific research. NIH contends that the absences of the PI were not approved nor was a substitute PI. NIH also disputes the "science" was performed and contends that essentially no new information on the research proposed in the grant was produced. TJU further contends that OMB Circular No. A-133 audits of TJU, conducted by outside auditors for periods in question, found that TJU complied in all material respects with grant requirements.

2. GRANT 36552

H. In December of 1996, Wu, a researcher at TJU, made allegations that Duan (who was employed as a post-doctoral researcher at TJU in the Division of Infectious Diseases), engaged in scientific misconduct and that certain published articles contained false scientific information relating to research Grant 36552, which was awarded to TJU by the National Institute of Allergy and Infectious Diseases ("NIAID") of NIH in September of 1994.

I. Upon learning of these allegations, TJU pursuant to its Policy and Procedures for Responding to Alleged Misconduct

in Research convened the appropriate committees to investigate the allegations. After due deliberation and evaluation of the available relevant evidence, the Ad Hoc Investigation Committee ("Committee"), which was comprised of knowledgeable scientists, concluded that no research misconduct had been committed, but that Duan made false statements to the Committee. The Committee issued findings and recommendations in a report dated September 29, 1997, which TJU states it has implemented. The Committee's report was forwarded by TJU to ORI for oversight pursuant to 42 C.F.R. Part 50, Subpart A. ORI oversight of TJU's investigation into this matter was suspended pending resolution of a related civil action.

J. TJU subsequently learned that in May of 1997 Wu filed a qui tam lawsuit (under seal) in the United States District Court for the Eastern District of Pennsylvania (Civil Action No. 97-3396), which made allegations similar to those considered by the TJU Ad Hoc Investigation Committee, and along with Duan, named TJU and Pomerantz (Chief of the Division of Infectious Diseases at TJU and the Director of TJU's Center for Human Virology) as additional defendants. An investigation was conducted of the allegations by the United States Attorney's Office for the Eastern District of Pennsylvania, based in part

upon materials turned over by TJU from its own internal investigation of Wu's allegations.

K. The United States contends that as a result of its investigation, it has claims against Duan, TJU and Pomerantz for statements/research data contained in the initial application for Grant 36552 and subsequent applications for continuance of the grant and progress reports that were based, in part, on falsified and/or fabricated research data, or data that are non-existent that were submitted from September 1994 through May 1998. The United States further contends that had it known that the data were allegedly falsified and/or fabricated, or that data did not exist to support the findings that were made in certain publications and the grant application, NIAID would never have initially funded nor continued to fund Grant 36552. A total of \$836,712 was paid by NIAID to TJU for Grant 36552 during a four-year period. The allegations contained herein are referred to as the "Duan Covered Conduct".

L. The United States contends that it has certain civil claims against Duan, TJU, and Pomerantz under the False Claims Act, 31 U.S.C. §§3729-3733, and other federal statutes and/or common law doctrine for the Duan Covered Conduct.

M. The United States also contends that it has certain administrative claims and debarment actions against Duan, TJU, and Pomerantz under the provisions for eligibility to receive federal grants and contract funds, 45 C.F. R. Part 76 and 48 C.F.R. Part 9.4 for the Duan Covered Conduct. ORI has retained continuing oversight of the internal investigation performed by TJU regarding allegations of research misconduct that pertain solely to Duan, and not to Pomerantz and TJU.

N. Duan, TJU, and Pomerantz do not admit the contentions of the United States as set forth in Paragraphs K, L and M, and deny any wrongdoing or liability with respect to the allegations against them.

3. TJU'S COMPLIANCE EFFORTS

O. As part of its compliance efforts in the areas of scientific research and grants administration, TJU has adopted and is continuing to adopt and implement new policies and procedures for cost transfers, non-reimbursable expenditures for federally-funded programs, costing guidelines for sponsored projects, cost sharing and matching grants, emergency use of investigational drugs and biologicals, IRB review of adverse events and a Code of Conduct and conflict of interest

statements. These policies and procedures are being made available to NIH.

P. In April 1998, TJU implemented a training program for all responsible staff, including all Jefferson Medical College faculty and key administrative personnel involved in supported research, and provided instruction in the following research areas including, but not limited to: (1) risks of noncompliance; (2) rules, regulations and TJU policies and procedures governing research; (3) delineation of roles and responsibilities; (4) effort certification; and (5) signing authority. According to TJU, since April 1998 over 550 of TJU's research staff have attended presentations on this training program.

Q. On January 26, 1999, TJU and the NIH conducted a joint one day grant administration program at TJU which focused on the following areas including, but not limited to: (1) misconduct in research; (2) data stewardship; (3) authorship and mentorship; (4) ethics; and (5) conflict of interest.

R. In January 1999, TJU began implementing a new system for effort certification, led by the Assistant Compliance Officer, the Director of Research Compliance, and the Effort

Coordinator, who administers the effort certification program for sponsored projects.

4. FULL AND FINAL SETTLEMENT

S. In order to avoid the delay, uncertainty, inconvenience and expense of protracted litigation of the above referenced claims, the Parties have reached a full and final settlement as set forth below. This Agreement shall not be construed as an admission of any liability or wrongdoing on the part of TJU, Croce, Glick, Pomerantz and Duan, or constitute an adjudication of any issue of fact or law.

III. TERMS AND CONDITIONS

NOW, THEREFORE, in consideration of the mutual promises, covenants, and obligations set forth below, and for good and valuable consideration as stated herein, the Parties agree as follows:

1. TJU agrees to pay to the United States Two Million Six Hundred Thousand Dollars (\$2,600,000) (the "Settlement Amount"), by electronic funds transfer pursuant to written instructions to be provided by United States. TJU agrees to make this electronic funds transfer upon execution of the Settlement Agreement.

2. TJU agrees to implement additional policies and procedures to improve its administration and accounting of research grants/projects funded by HHS in order to assure compliance with all federal laws and regulations pertaining to the award and receipt of federal grant funds. Upon execution of this Settlement Agreement and in order to assure compliance, TJU agrees to immediately implement an Institutional Integrity Agreement ("IIA") which is attached hereto and incorporated herein as Exhibit A.

3. TJU will also implement the following policies and procedures:

(a) TJU will make available for interview to the OIG, ORI, and the NIH and any subdivisions therein, ("Appropriate Agency of the United States"), all Principal Investigators and other key grant personnel and administrators ("Responsible Parties") in the event that any of these federal entities has reason to believe that falsification, fabrication, plagiarism or other types of misrepresentation of data or other information pertinent to a grant award has occurred--such interview to occur at a reasonable time and place. TJU will encourage such interviews as part of its IIA. However, if a Responsible Party, consistent with the rights and privileges of such individual,

refuses to be interviewed based upon an individual decision and/or advice of counsel, TJU will not be in breach of this Agreement and/or the IIA if the interview does not occur. In the event that the interview with the Responsible Party requires the presence of an individual with scientific knowledge, as determined by the United States, a representative of the United States that is knowledgeable and conversant with any science that is the subject of the research grant will be present during any such interview. Counsel for TJU may be present during the interview if TJU counsel is representing the Responsible Party.

(b) TJU will appoint the grants administrator for the Department of Microbiology-Immunology as a member of the Compliance Committee and TJU agrees to make that individual available for interview by the United States upon request by the United States.

(c) TJU agrees to adopt a policy as part of the IIA on manuscript authorship in accordance with Exhibit B, attached hereto and incorporated herein.

Nothing in this paragraph 3 shall obligate the United States to notify TJU of any allegations, inquiry, civil and/or criminal investigations, or qui tam filings related to falsification, fabrication, plagiarism or other types of

misrepresentation of data or other information pertinent to a grant award or misrepresentation of data. Nothing in this paragraph shall relieve TJU of its responsibility to comply with all federal laws, regulations and published policies governing investigations into scientific misconduct and/or grant administration. Any requirements found in this Agreement and/or the IIA are in addition to existing federal requirements.

4. TJU has represented to the NIH that it is taking appropriate corrective actions to establish and maintain a grants management and administration program satisfactory to the NIH as required by the October 3, 1996 letter from Geoffrey E. Grant, Acting Director, Office of Policy for Extramural Research Administration, NIH, to Paul C. Brucker, M.D., President, TJU, and the November 21, 1996 letter from Mr. Grant to Alan B. Kelly, Esquire, TJU. TJU shall report to NIH on the implementation of its corrective actions as required by these letters. Both TJU and NIH are committed to a continuing collaborative relationship whereby NIH will provide technical assistance to TJU in connection with the development and implementation of TJU's corrective action plan. Because TJU was designated by NIH as an Exceptional Organization pursuant to 45 C.F.R. §74.14, a primary objective of TJU's corrective action

plan is the prompt removal of said designation. Accordingly, the following process and standards will be used by NIH to remove the Exceptional Organization designation:

(a) To the extent TJU has not done so, TJU will develop and implement policies, procedures and other materials consistent with the laws, regulations and NIH published policies governing sponsored programs in the areas addressed in the above-referenced letters.

(b) TJU will submit all applicable policies, procedures and other materials to NIH. Within 180 days of TJU's final submission, and notification by TJU of such final submission, NIH will review all applicable policies, procedures and materials submitted by TJU for compliance with applicable law, regulations and NIH published policies and provide TJU specific comments identifying critical revisions to the policies, procedures and materials. All policies, procedures, and materials submitted by TJU, including critical revisions identified by NIH, will be considered TJU's corrective actions.

(c) Subsequent to TJU's implementation of corrective actions under paragraph (b), and no earlier than the completion of the first annual audit required by the Institutional Integrity Agreement and subsequent review by an Independent

Review Organization ("IRO"), at TJU's request NIH will conduct an Effectiveness Site Visit at a scheduled time mutually convenient for both TJU and NIH, using their best efforts to commence the Effectiveness Site Visit no later than 90 days following TJU's request.

(d) Within 90 days of the Effectiveness Site Visit, NIH will determine, in its sole discretion, and notify TJU of the following: (1) Based on its assessment, whether TJU has implemented appropriate corrective actions that are operating effectively at a demonstrated level of substantial compliance with TJU's policy and procedures, including critical revisions; and (2) NIH's decision on removing TJU's designation as an Exceptional Organization, consistent with 45 C.F.R. §74.14.

(e) NIH may extend the time frames in this paragraph 4 up to an additional 60 days with notification to TJU and only for good cause.

5. The United States and TJU agree that the statement attached as Exhibit C hereto is a true and accurate summary of the current state of the science with respect to the scientific matters at issue relating to Grant 35662.

6. The United States and TJU and Pomerantz shall make a good faith effort to obtain publication of the correction

statement attached as Exhibit C by all journals that previously published the results of the research performed at TJU. The United States will not seek to require any further correction or any retraction of the previously published work related to Grant 36552 by TJU, and agrees that any publication of the correction statement by any journal should only be identified as a correction.

7. Promptly after this Agreement is executed, and after payment in full of the Settlement Amount, the United States will notify the Court in the Civil Action, simultaneously, that (a) the United States is intervening in Civil Action No. 97-3396 for the purposes of joining with the Relator Wu in stipulating to a dismissal with prejudice of this action and that (b) notwithstanding such intervention, all parties have reached a settlement, and pursuant to this settlement, all parties have stipulated that the claims in Civil Action No. 97-3396 are dismissed with prejudice.

8. Subject to the terms of this Agreement and upon receipt of the payment described in paragraph 1, the United States agrees to fully and finally release TJU and its current and former directors and officers, employees and agents, Croce and Glick, from civil or administrative monetary claims the

United States has asserted or may assert, under the False Claims Act, 31 U.S.C. §§ 3729-3733; the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812; or the common law theories of payment by mistake, unjust enrichment, breach of contract and fraud, for the Grant 55541 Covered Conduct and for the Anderson Audit described above.

9. Subject to the terms of this Agreement and upon receipt of payment described in paragraph 1, the United States agrees to fully and finally release TJU and its current and former directors and officers, employees and agents, Pomerantz and Duan from civil or administrative monetary claims the United States has asserted or may assert, under the False Claims Act, 31 U.S.C. §§ 3729-3733; the Program Fraud Civil Remedies Act, 31 U.S.C. §§3801-3812; or the common law theories of payment by mistake, unjust enrichment, breach of contract and fraud, for the Duan Covered Conduct.

10. In consideration of the obligations of TJU, Croce, Glick, Pomerantz and Duan set forth in this Agreement and the IIA, and conditioned upon TJU's payment in full of the Settlement Amount as set forth in paragraph 1, HHS agrees to release and refrain from instituting, directing or maintaining any debarment action under 45 C.F.R. Part 76 and 48 C.F.R.

Part 9.4 or administrative claim against TJU, Croce, and Glick for the Grant 55541 Covered Conduct and for the Anderson Audit; and against TJU, Pomerantz and Duan for the Duan Covered Conduct, except as reserved in Paragraph 11 below.

11. Notwithstanding any term of this Agreement, specifically reserved and excluded from the scope and terms of this Agreement as to any entity or person are the following:

- (1) Any civil, criminal or administrative claims arising under Title 26, U.S. Code (Internal Revenue Code);
- (2) Any criminal liability;
- (3) Except as set forth in the Covered Conduct described above and released, any administrative liability;
- (4) Any liability to the United States (or its agencies) for any conduct except as set forth in the Covered Conduct described above and released;
- (5) Any claims based upon such obligations as are created by this Agreement;
- (6) Any express or implied warranty claims or other claims for defective or deficient products or services, including quality of goods and services, provided by TJU;

(7) Any claims for personal injury or property damage or for other consequential damages except as set forth in the Covered Conduct described above and released; and

(8) Any claims based on a failure to deliver items or services due, except as set forth in the Covered Conduct described above and released.

(9) Any findings made or administrative action taken by the United States, resulting from ORI's continuing oversight in ORI 97-07 of the investigation of allegations of research misconduct against Duan, except as to the publication of any journal correction which shall be in accordance with paragraph 6.

12. TJU, Croce, Glick, Pomerantz and Duan fully and finally release the United States, its agencies, employees, servants, and agents from any claims (including attorneys fees, costs, and expenses of every kind and however denominated) which TJU, Croce, Glick, Pomerantz and Duan have asserted, or may assert against the United States, its agencies, employees, servants, and agents, related to the Covered Conduct described above and the United States' investigation and prosecution thereof.

13. TJU, Pomerantz and Duan fully and finally release Relator Wu from any claims (including attorneys fees, costs, and expenses of every kind and however denominated) which TJU, Pomerantz and Duan have asserted, or may have asserted against Wu, including but not limited to the litigation captioned Thomas Jefferson University v. Yong Wu, Civil Action No. 00-923 (Eastern District of Pennsylvania) (petition for removal) and the case captioned Thomas Jefferson University v. Yong Wu, July Term, 1999, No. 3772 (Philadelphia Court of Common Pleas).

14. Wu fully and finally releases TJU, its current and former directors and officers, employees and agents, Pomerantz and Duan from any claims (including attorneys fees, costs, and expenses of every kind and however denominated) which Wu has asserted, or may have asserted against TJU, Pomerantz and Duan relating to the Duan Covered Conduct as well as any retaliation claim against TJU, its current and former directors and officers, employees and agents.

15. TJU, Croce, Glick, Pomerantz and Duan agree that all costs (as defined in 45 C.F.R. § 74.27, 45 C.F.R. Part 74 and 45 C.F.R. Part 92), whether direct or indirect incurred by or on behalf of TJU, Croce, Glick, Pomerantz and Duan or their agents, employees, or former employees in connection with: (1) the

matters covered by this Agreement, (2) the Government's audit(s) and civil and any criminal investigation(s) of the matters covered by this Agreement, (3) TJU's investigation, defense, and corrective actions undertaken in response to the Government's audit(s) and civil and any criminal investigation(s) in connection with the matters covered by this Agreement (including attorney's fees) and the IIA, including the obligations undertaken pursuant to the IIA incorporated into this Settlement Agreement, to the extent undertaken in response to the government's audit(s) and civil and criminal investigation(s) in connection with the matters covered by this Agreement, including attorney's fees; (4) the negotiation of this Agreement, and (5) the payment made pursuant to this Agreement, are unallowable costs under the cost principles applicable to government grants, contracts, cooperative agreements, and other agreements to which 45 C.F.R. Part 74 and 45 C.F.R. Part 92 applies (hereafter, "unallowable costs"). These unallowable costs will be separately estimated and accounted for by TJU and TJU will not charge such unallowable costs directly or indirectly to any grants, contracts, cooperative agreements, or other agreements with the United States or seek payment for such unallowable costs through any cost report, cost statement, information

statement or payment request submitted by TJU or any of its departments or agencies. The parties agree that nothing in this Agreement shall constitute a waiver of any rights the United States may have under 45 C.F.R. § 74.27, 45 C.F.R. Part 74 and 45 C.F.R. Part 92. TJU, Croce, Glick, Pomerantz and Duan further agree that within 60 days of the effective date of this Agreement they will identify to applicable United States grantors any unallowable costs (as defined above in this paragraph as (1) through (5)) included in payments previously sought from the United States, including, but not limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by TJU, any of its departments, Croce, Glick, Pomerantz or Duan, and will request, and agree, that such cost reports, cost statements, information reports or payment requests, even if already settled, be adjusted to account for the effect of the inclusion of the unallowable costs. TJU, Croce, Glick, Pomerantz and Duan agree that the United States will be entitled to recoup from each of them any overpayment as a result of the inclusion of such unallowable costs on previously-submitted costs reports, information reports, cost statements or requests for payment. Any payments due after the adjustments have been

made shall be paid to the United States pursuant to the direction of the Department of Justice, and/or the affected agencies. The United States reserves its rights to disagree with any calculations submitted by TJU, any of its departments, Croce, Glick, Pomerantz or Duan on the effect of inclusion of unallowable costs (as defined above in this paragraph as (1) through (5)) on any of their cost reports, cost statements or information reports. Nothing in this Agreement shall constitute a waiver of the rights of the United States to examine or reexamine the unallowable costs described in this Paragraph.

16. In the event that TJU, Croce, Glick, Pomerantz and/or Duan fail to comply in good faith with any of the terms of this Agreement, or should any of TJU, Glick, Croce, Pomerantz or Duan's representations or warrants be materially false ("Alleged Breach"), the United States may, at its sole discretion, exercise one or more of the following rights against the defaulting party:

(1) seek specific performance of this Agreement and in addition, recover reasonable attorney's fees and costs;

(2) impose any remedy contained in the IIA in accordance with the procedures set forth therein;

(3) exercise any other right granted by law, including debarment from participation in federal programs or exercise any right granted or cognizable at common law or equity, including injunctive relief. The United States agrees that it will first give written notice of any Alleged Breach, specifying the circumstances of the Alleged Breach, and provide the alleged defaulting party an opportunity to cure any Alleged Breach within thirty (30) days of receipt of such written notice. In the event the United States elects to rescind the Agreement, the Parties do not waive any defenses, claims or causes of action which were available as of the date of execution of this Agreement by the Parties.

17. TJU, Croce, Glick, Pomerantz and Duan agree not to intimidate or take any retaliatory action against any individual or individuals who cooperated with the investigations and/or who cooperate(s) with the United States throughout the pendency of this Agreement and the IIA.

18. This Agreement is intended to be for the benefit of the Parties, their successors and assigns, and by this instrument the Parties do not release any claims against any other person or entity.

19. Each party to this Agreement will bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

20. TJU, Croce, Glick, Pomerantz and Duan represent that this Agreement is freely and voluntarily entered into without any degree of duress or compulsion whatsoever.

21. This Agreement is governed by the laws of the United States. The Parties agree that the exclusive jurisdiction and venue for any dispute arising between and among the Parties under this Agreement will be the United States District Court for the Eastern District of Pennsylvania, except any dispute under the IIA shall be subject to the dispute resolution provisions therein, and any dispute with NIH shall be subject to the administrative process of NIH as set forth in paragraph 4 of this Agreement which shall be resolved in good faith by TJU and NIH. Nothing in this Agreement shall be construed to create or denigrate any rights to administrative and/or judicial review otherwise available to the Parties to the extent allowed by law.

22. This Agreement and the Exhibits constitute the complete agreement between the Parties. There are no restrictions, promises, representations, warranties, covenants, or undertakings other than those expressly set forth or referred

to in this Agreement and the Exhibits. This Agreement, together with the Exhibits, supersedes any and all prior agreements and understandings between the Parties with respect to this subject matter. This Agreement may not be amended except by written consent of the Parties, except that only TJU and OIG-HHS must agree in writing to modification of the IIA, pursuant to the terms set forth in the IIA.

23. The undersigned individuals signing this Agreement on behalf of the United States, TJU, Croce, Glick, Pomerantz, Duan and Wu represent and warrant that they are authorized by the United States, TJU, Croce, Glick, Pomerantz, Duan and Wu to execute this Agreement.

24. This Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same agreement.

IN WITNESS WHEREOF, the parties have executed this Agreement.

UNITED STATES OF AMERICA:

THOMAS JEFFERSON UNIVERSITY:

Michael R. Stiles 5/19/00
MICHAEL R. STILES Date
United States Attorney

Date

James G. Sheehan 5/19/00
JAMES G. SHEEHAN Date
Assistant United States Attorney
Chief, Civil Division

CARLO CROCE, M.D.:

Date

David R. Hoffman 5/19/00
DAVID R. HOFFMAN Date
Assistant United States Attorney

JEROLD GLICK:

Date

ROGER POMERANTZ, M.D.

LEWIS MORRIS Date
Assistant Inspector General
Office of Counsel to the
Inspector General
Office of Inspector General
United States Department
of Health and Human Services

Date

Terrence J. Tychan Date
Deputy Assistant Secretary for
Grants and Acquisition Management

IN WITNESS WHEREOF, the parties have executed this Agreement.

UNITED STATES OF AMERICA:

THOMAS JEFFERSON UNIVERSITY:

MICHAEL R. STILES Date
United States Attorney

Paul C. Brucker 5/18/00

PAUL C. BRUCKER, MD Date
PRESIDENT

JAMES G. SHEEHAN Date
Assistant United States Attorney
Chief, Civil Division

CARLO GROCE, M.D.:
[Signature]

Date

DAVID R. HOFFMAN Date
Assistant United States Attorney

JEROLD GLICK:
Jerold Glick 5/18/00

Date

LEWIS MORRIS Date
Assistant Inspector General
Office of Counsel to the
Inspector General
Office of Inspector General
United States Department
of Health and Human Services

ROGER POMERANTZ, M.D.
[Signature] 5/18/00

Date

Terrence J. Tychan Date
Deputy Assistant Secretary for
Grants and Acquisition Management

IN WITNESS WHEREOF, the parties have executed this Agreement.

UNITED STATES OF AMERICA:

THOMAS JEFFERSON UNIVERSITY:

MICHAEL R. STILES Date
United States Attorney

Date

JAMES G. SHEEHAN Date
Assistant United States Attorney
Chief, Civil Division

CARLO CROCE, M.D.:

Date

DAVID R. HOFFMAN Date
Assistant United States Attorney

JEROLD GLICK:

Date

L Morris 5/18/00

LEWIS MORRIS Date
Assistant Inspector General
Office of Counsel to the
Inspector General
Office of Inspector General
United States Department
of Health and Human Services

ROGER POMERANTZ, M.D.

Date

for Charles Gale 5/18/00

Terrence J. Tychan Date
Deputy Assistant Secretary for
Grants and Acquisition Management

YONG WU, M.D.

SINGKUN DUAN, M.D.


Date
5-17-00

Date

Approved and So Ordered

United States District Court Judge

YONG WU, M.D.

LINGXUN DUAN, M.D.

Date


Date 5/19/06

Approved and So Ordered

United States District Court Judge

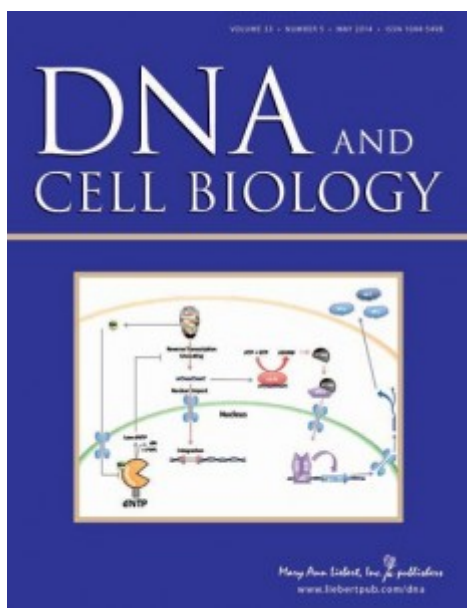
Exhibit D

Retraction Watch

Tracking retractions as a window into the scientific process

Retractions 3 and 4 appear for researcher facing criminal probe; OSU co-author won't face inquiry

[with 32 comments](#)



[Alfredo Fusco](#), a cancer researcher in Italy who is facing a criminal investigation for fraud, has had two more papers retracted.

Here's the *Cell Death & Disease* [notice](#) for "High-mobility group A1 protein inhibits p53-mediated intrinsic apoptosis by interacting with Bcl-2 at mitochondria:"

The Editorial Board of *Cell Death and Disease* is retracting the above article (PMID 22932725).

A reader contacted the Editors about apparent duplications in Figures 1b and 2c, and possible splicing of an image in Figure 3c. Concerns were subsequently raised about the similarity of the tubulin loading controls in Figure 1b to those that appeared in Figure 1c of *Cell Death and Differentiation* 2006; **13**: 1554–63 (PMID 16341121), a paper that was retracted by the authors on 6 December 2013.

Because the Authors were unable to provide the original source files that were used to generate the figures in question, the Editorial Board is retracting this publication.

The paper has been cited nine times, according to Thomson Scientific's Web of Knowledge.

Here's a [notice](#) from *DNA and Cell Biology*, which is unfortunately behind a paywall:

The article entitled "Targeted Disruption of the Murine Homeodomain-Interacting Protein Kinase-2 Causes Growth Deficiency *In Vivo* and Cell Cycle Arrest *In Vitro*," by Trapasso et al., 2009;28(4);doi: 10.1089/dna.2008.0778, pp 161–167, is being officially retracted from *DNA and Cell Biology*.

Data presented in Figure 1 appear to have been manipulated.

We regret any inconvenience this error may have caused.

The *DNA and Cell Biology* paper has been cited 11 times.

Fusco's other retractions were [from the Journal of Clinical Investigation](#) and [Cell Death and Differentiation](#).

We've also obtained a [letter from Ohio State University](#), where one of Fusco's co-authors on the *DNA and Cell Biology* paper works, to pseudonymous whistleblower Clare Francis. That co-author, Carlo Croce, has written several papers with Fusco. Here's the text, in which an administrator says OSU sees no reason to investigate, and that the Office of Research Integrity agrees:

The Ohio State University received your additional allegations against university faculty member Carlo M. Croce Ph.D., which were detailed in the emails you sent on December 12, 2013 and December 14, 2013. As noted in my letter to you dated December 12, 2013, the University reviewed the manuscripts numbered 1, 3, and 4 in your email of December 12, 2013 and determined that the manuscripts were not generated at Ohio State. Specifically, the corresponding authors for the manuscripts are not employed by the Ohio State University. Further, although Dr. Croce is a co-author on the three manuscripts, neither Dr. Croce nor any other Ohio State employee generated or provided any data for the figures in question, nor were they involved in the generation of the figures. In view of these facts, any questions regarding the figures in these papers would need to be addressed by the corresponding authors and their home institutions. Pertaining to manuscript 2 in your email of December 12, 2013, that manuscript was part of the original set of allegations (initially numbered 32) originally sent by you to the Office of Research Integrity (ORI) and then forwarded by you to Ohio State University on November 17, 2013. The manuscript was reviewed by the ORI and per the ORI there is no further action needed. As such, the Ohio State University considers this matter closed.

Of note: In the Terry Elton case, the ORI said [OSU hadn't gone far enough](#). OSU concluded its letter to Francis:

Please note that the Institution considers continued activities in this vein as constituting frivolous allegations and a waste of University and State resources.

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June 6, 2014
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Group investigated by University of Louisville corrects lung cancer paper after retracting six others
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In "am j resp cell mol bio"

Written by Ivan Oransky

May 5th, 2014 at 9:30 am

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Case: 2:17-cv-00402-JLG-EPD Doc #: 15-1 Filed: 07/10/17 Page: 38 of 74 PAGEID #: 284
« [Weekend reads: Retraction Watch on NPR: “hysteria” over replication; when a paywall might be a good thing](#)
[Dubai-ous: Journal yanks surgery paper for consent, data issues](#) »

Comments



• *SD* May 5, 2014 at 10:01 am

Carlo Croce again? The author of the one of the silliest papers ever published Nature. 1989 Nov 9;342(6246):195-8.

The bcl-2 gene encodes a novel G protein.

Haldar S1, Beatty C, Tsujimoto Y, Croce CM.

<http://www.nature.com/nature/journal/v342/n6246/abs/342195a0.html>

It should have been retracted long ago. I recommend it for a good laugh.

[Reply](#) [Link](#) [Quote](#)



• *Dan Zabetakis* May 5, 2014 at 10:15 am

I'm surprised by the response from Ohio State University. Do they not adhere to the ethical principle that all authors are responsible for the whole of any scientific paper? The detached, legalistic denial does not see either adequate or appropriate given the context.

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• *SD* May 5, 2014 at 6:51 pm

It looks to me that lanes 3, 4, and 5 in the beta-actin panel were copied into lanes 6, 7, and 8 of Figure 1B of “WWOX gene restoration prevents lung cancer growth in vitro and in vivo”

Muller Fabbri, Dimitrios Iliopoulos, Francesco Trapasso, Rami I. Aqeilan, Amelia Cimmino, Nicola Zanesi, Sai Yendamuri, Shuang-Yin Han, Dino Amadori, Kay Huebner, and Carlo M. Croce

<http://www.pnas.org/content/102/43/15611.long>

No Fusco, but F. Trapasso and C. Croce are authors common to the DNA and Cell Biology and PNAS articles. The PNAS article should be retracted as well.

Trapasso and Croce have been coauthors on 49 Pubmed archived articles. Fusco and Croce are coauthors on 44, and the three have been coauthors on 10. Trapasso and Fusco are coauthors on 36.

Is Peter Vogt of the The Scripps Research Institute, the editor of the PNAS article, aware of these issues?

What responsibility does a principal investigator have for the obviously manipulated data emerging from his laboratory in articles with his name on them?

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• *david hardman* May 15, 2014 at 2:26 am

Proc Natl Acad Sci U S A. 2012 Oct 9;109(41):16570-5.

Pubpeer comment on a paper where CM Croce is one of the two corresponding authors.

<https://pubpeer.com/publications/23012423>

For reference:

Proc Natl Acad Sci U S A. 2012 Oct 9;109(41):16570-5. doi: 10.1073/pnas.1207917109. Epub 2012 Sep 24.

MiR-494 is regulated by ERK1/2 and modulates TRAIL-induced apoptosis in non-small-cell lung cancer through BIM down-regulation.

Romano G1, Acunzo M, Garofalo M, Di Leva G, Cascione L, Zanca C, Bolon B, Condorelli G, Croce CM.

PMID: 23012423

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• *SD* May 28, 2014 at 6:39 pm

Some more Croce history—he doesn't have a good history with supervision of collaborators.

<http://books.google.com/books?id=IFqxBJNuET8C&q=croce#v=snippet&q=croce&f=false>

http://articles.philly.com/2000-05-20/news/25618843_1_gene-therapy-research-gene-therapy-legal-costs

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• *SD* May 28, 2014 at 6:50 pm

The court document on Thomas Jefferson and Croce

http://healthsci.org/USexrelYWu/2_USexrelYongWu_Settlement_Agreement.pdf

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• *SD* May 29, 2014 at 1:20 pm

JBC “Correction” for Croce and Fusco

POZ-, AT-hook-, and zinc finger-containing protein (PATZ) interacts with human oncogene B cell

lymphoma 6 (BCL6) and is required for its negative autoregulation.
Raffaella Pero, Dario Palmieri, Tiziana Angrisano, Teresa Valentino, Antonella Federico, Renato Franco, Francesca Lembo, Andres J. Klein-Szanto, Luigi Del Vecchio, Donatella Montanaro, Simona Keller, Claudio Arra, Vasiliki Papadopoulou, Simon D. Wagner, Carlo M. Croce, Alfredo Fusco, Lorenzo Chiariotti and Monica Fedele
VOLUME 287 (2012) PAGES 18308–18317

“Western blot images representing PATZ, BCL6, and tubulin in Fig. 6C did not accurately represent the experimental results. Different lanes were erroneously duplicated. Lane 3 of the PATZ panel was duplicated in lane 7; lane 4 of the PATZ panel was duplicated in lanes 5 and 6; lane 1 of the BCL6 panel was duplicated in lane 2; lane 4 of the tubulin panel was duplicated in lane 7; and lane 5 of the tubulin panel was duplicated in lane 6. The authors have provided an image from a replicate experiment. This correction does not affect the interpretation or conclusions of this work.”

<http://www.jbc.org/content/289/21/14966.full>

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• *fernandopessoa* October 19, 2015 at 10:17 am

2015 Mega-correction for
Cancer Lett. 2010 May 28;291(2):230-6. doi: 10.1016/j.canlet.2009.10.017.
Fhit loss in lung preneoplasia: relation to DNA damage response checkpoint activation.
Cirombella R1, Montrone G, Stoppacciaro A, Giglio S, Volinia S, Graziano P, Huebner K, Vecchione A.
Author information
1Division of Pathology, II University of Rome La Sapienza, Ospedale Santo Andrea, Rome, Italy..

<https://pubpeer.com/publications/499D4D40914B863806C7A6E10B34AE#fb38826>

[Reply Link Quote](#)



• *fernandopessoa* July 15, 2016 at 3:24 am

3rd retraction for Carlo M Croce.

2016 retraction.

<http://www.jbc.org/content/291/29/14914.full>

<https://pubpeer.com/publications/0E3ED839EE93ED96AD45AD63AFFCEE>

J Biol Chem. 2009 Oct 2;284(40):27487-99. doi: 10.1074/jbc.M109.036541. Epub 2009 Jul 29.
Unique microRNA profile in end-stage heart failure indicates alterations in specific cardiovascular signaling networks.
Naga Prasad SV1, Duan ZH, Gupta MK, Surampudi VS, Volinia S, Calin GA, Liu CG, Kotwal A, Moravec CS, Starling RC, Perez DM, Sen S, Wu Q, Plow EF, Croce CM, Karnik S.
Author information
1Department of Molecular Cardiology, Lerner Research Institute, Cleveland Clinic, Cleveland, Ohio 44195, USA.

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• *fernandopessoa* March 9, 2017 at 11:23 am

The letter from Ohio State University states
“faculty member Carlo M. Croce Ph.D.”
yet according to the New York Times and his own website he does not have a Ph.D..

https://www.nytimes.com/2017/03/08/science/cancer-carlo-croce.html?_r=0

“Dr. Croce, who has a medical degree but no Ph.D.”.

<https://medicine.osu.edu/cancer-biology-genetics/directory/medical-genetics/croce-carlo/pages/index.aspx>

“Education & Training
1969 Doctor of Medicine, University of Rome La Sapienza”

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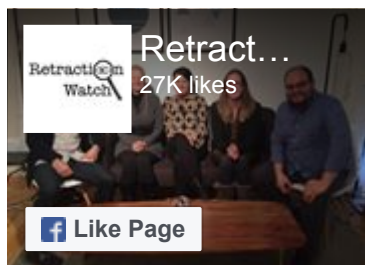
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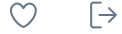
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Exhibit E

IN THE COMMON PLEAS COURT OF
FRANKLIN COUNTY, OHIO

CARLO M. CROCE	:	
2140 Cambridge Boulevard	:	
Columbus, Ohio 43221	:	Case No. _____
	:	
Plaintiff,	:	Judge
	:	
v.	:	
	:	
DAVID A. SANDERS	:	JURY TRIAL DEMANDED
324 Jefferson Drive	:	
West Lafayette, Indiana 47906	:	
	:	
Defendant.	:	
	:	

COMPLAINT

Plaintiff, Carlo M. Croce, for his complaint against Defendant David A. Sanders, alleges as follows:

INTRODUCTION AND PARTIES

1. Plaintiff, Carlo M. Croce, M.D. is the John W. Wolfe Chair, Human Cancer Genetics at The Ohio State University (“OSU”). He is also the Director of the Human Cancer Genetics Program, the Director of the Institute of Genetics, Professor of Internal Medicine, and Chair of the Department of Molecular Virology, Immunology & Medical Genetics, all at OSU.

2. Dr. Croce is a pioneer of research into the genetic mechanisms of cancer. He began his research into genetic anomalies in cancer at a time when little was known of the human genome. His decades-long work thereafter uncovered the early events involved in the pathogenesis of leukemias and lymphomas, and lung, nasopharyngeal, head and neck, esophageal, gastrointestinal and breast cancers. His discoveries have led

to revolutionary innovations in the development of novel and successful approaches to cancer prevention, diagnosis, monitoring and treatment, based on gene-target discovery, verification and rational drug development. For example, his discovery of the BCL2 gene and of the mechanisms of its activation have led to the discovery of a drug, ABT-199 or Venetoclax, for the treatment of chronic lymphocytic leukemia, the most common human leukemia.

3. Since 1975, Dr. Croce has received more than 64 awards for his research and discoveries in the field of genetics, including the Mott Award from the General Motors Cancer Foundation (1993), the Pezcoller Award from the American Association for Cancer Research (1999), the Clowes Memorial Award from the American Association for Cancer Research for his discoveries of the molecular mechanisms of leukemia (2006); and the InBev-Baillet Latour Fund International Health Prize (2013) and the 30th Annual Jeffrey A. Gottlieb Memorial Award for “his discovery that non-coding RNAs are involved in cancer pathogenesis” (2013) Most recently, it was announced on January 18, 2017, that Dr. Croce has been selected as the 2017 recipient of the American Association for Cancer Research Margaret Foti Award which “recognizes a true champion of cancer research, an individual who embodies the sustained commitment of Margaret Foti to the prevention and cure of cancer,” and is “given to an individual whose leadership and extraordinary achievements in cancer research or in support of cancer research have made a major impact on the field.”

4. Dr. Croce has been a Member of the National Academy of Sciences for more than twenty years. Scientists are elected by their peers to membership in the National Academy of Sciences for their outstanding contributions to research. Dr. Croce

is also a Member of the American Academy of Arts and Sciences and a Member of the National Academy of Medicine. He is also a Fellow of the Academy of the American Association for Cancer Research, a Fellow of the American Association for the Advancement of Science, and a member of The National Academy of Inventors.

5. Other highly respected scientists in Dr. Croce's field have described Dr. Croce as a distinguished scientist who has made major contributions to cancer research. One such scientist stated that "[o]ur current understanding of genetic mechanisms in cancer is based to a large extent on Croce's fundamental discoveries on chromosomal rearrangements and on the unique role of microRNAs in cancer," and "[h]is discoveries are fundamental guideposts for current and future efforts to defeat cancer."

6. Dr. Croce's research has been reported in the major research journals, including Nature, Science, Cell, Cancer Cell, Journal of Clinical Oncology, The Lancet Oncology, Journal of the National Cancer Institute and Cancer Research, and the Proceedings of the National Academy of Sciences, among many others. Dr. Croce is one of the most cited scientists in the world.

7. As is standard in the scientific research community, Dr. Croce's name will typically appear as the first or last author on those papers for which the research was performed in his lab and which were written by him or by those working under his supervision. Dr. Croce is the first or last author on more than 560 papers.

8. As is also common in the scientific research community, Dr. Croce is often listed as a co-author of scientific papers where the research did not take place in his lab or under his supervision, and he did not participate in the task of writing the paper. In many of those papers, his participation was limited to the contribution of important

reagents or genetically altered mice. For example, Dr. Croce and his colleagues developed a number of transgenic and knockout mice, during the course of their research, which were also helpful to accelerating the research being conducted by others. The sharing of transgenic and knockout mice with other cancer researchers saved those researchers considerable time and resources and greatly facilitated their work; however, in such situations, Dr. Croce would have no control over either the work being performed or the publication of any results.

David A. Sanders PhD

9. Defendant, David A. Sanders, PhD, is an Associate Professor at Purdue University in the Department of Biological Sciences. On information and belief, Dr. Sanders has been an Associate Professor at Purdue for approximately twenty years.

10. On information and belief, Dr. Sanders has been the first author on two papers and the last author on about twenty-four.

JURISDICTION AND VENUE

11. Dr. Croce is a citizen of the United States and Ohio and a resident of Franklin County, Ohio.

12. Sanders is a resident of Tippecanoe County, Indiana.

13. This court has personal jurisdiction over Defendant pursuant to Ohio Revised Code §2307.382(A)(6) and Ohio Civil Rule 4.3(A)(9) because Defendant “caus[ed] tortious injury in this state to [Plaintiff] by an act outside this state committed with the purpose of injuring persons, when he might reasonably have expected that some person would be injured thereby in this state.”

14. Venue is proper in this court pursuant to Ohio Civil Rule 3(B)(7).

STATEMENT OF FACTS

15. On or about November 23, 2016, Dr. Croce received a letter from New York Times reporter James Glanz (“Glanz”). The letter was addressed to both Dr. Croce and his employer, The Ohio State University. In that letter, Mr. Glanz stated that he had questions he wanted to “put urgently” to Dr. Croce and OSU “as part of an article” Glanz was preparing.

16. Glanz’s letter included false and defamatory statements that Defendant Sanders made to Glanz about Dr. Croce. Defendant Sanders falsely stated to Glanz (and Glanz repeated in his letter to OSU) that “image fabrication, duplication and mishandling, and plagiarism in Dr. Croce’s papers is routine” and that Dr. Croce is “knowingly engaging in scientific misconduct and fraud.”

17. Dr. Croce has not engaged in “routine” “image fabrication, duplication or mishandling” or “plagiarism.” Nor has Dr. Croce “knowingly engag[ed] in scientific misconduct and fraud.”

18. Indeed, fewer than 3% of the more than 560 publications for which Dr. Croce is either the first or the last author have been the subject of any published correction. Not one of Dr. Croce’s scientific findings in any of those papers has ever been altered by any such published correction.

19. Defendant Sanders’ false and defamatory statements published to the New York Times reporter and republished by that reporter to OSU reflect injuriously on Dr. Croce’s reputation and adversely affect Dr. Croce in his profession as a scientist and leading cancer researcher. Sanders knew or should have known that those false and defamatory statements would be republished in Ohio.

20. Defendant Sanders expressly aimed his false and defamatory statements at Ohio and purposely availed himself of the privilege of causing a consequence in Ohio. Specifically, defendant Sanders knew or should have known at the time he published his false and defamatory statements about Dr. Croce that:

- a. Dr. Croce is an esteemed and distinguished professor and scientist who has been employed by OSU for thirteen years during which time he has been the John W. Wolfe Chair in Human Cancer Genetics at OSU; Professor and Chairman, Dept. of Cancer Biology and Genetics (formerly the Dept. of Molecular Virology, Immunology and Medical Genetics) at the OSU School of Medicine; the Director, Institute of Genetics at OSU; Director of Human Cancer Genetics Program at OSU; and since 2005, has held the title of Distinguished University Professor at OSU.
- b. Dr. Croce has received more than half of his approximately sixty-four awards while he has been at OSU.
- c. Dr. Croce's reputation was at the time of Sanders' false and defamatory statements and still is centered in Ohio and his professorship at OSU.
- d. Every scientific paper published during the thirteen years Dr. Croce has been at OSU and on which Dr. Croce has been listed as a coauthor has identified Dr. Croce as a professor at OSU.
- e. Tens of millions of dollars in federal and charitable research grants to OSU are the direct result of the fact that Dr. Croce is the principal investigator on the projects funded by those grants.

- f. Accordingly, any damage to Dr. Croce’s reputation resulting from Sanders’ defamatory statements will be felt immediately and directly by the State of Ohio and its educational institution, OSU, which was created by and exists under the statutory laws of the State of Ohio.
- g. Defendant Sanders knew or should have known all of these facts at the time that he published his false and defamatory statements about Dr. Croce. Sanders therefore knew or should have known that any damage to Dr. Croce’s reputation will be felt immediately and directly by and in the State of Ohio.

21. Sanders’ false and defamatory statements were intentionally directed to and impugned Dr. Croce’s research activities in Ohio. Sanders knew that the brunt of the harm from his false and defamatory statements would be suffered in Ohio.

22. Defendant Sanders caused tortious injury in this state by an act outside this state committed with the purpose of injuring an Ohio resident, when he knew or reasonably expected that an Ohio resident would be injured thereby in Ohio.

COUNT I

(Defamation per se)

23. Plaintiff repeats and incorporates by reference herein each of the preceding paragraphs.

24. Sanders’ false and defamatory statements that Dr. Croce “knowingly engag[es] in scientific misconduct and fraud,” and that “image fabrication, duplication and mishandling, and plagiarism in Dr. Croce’s papers is routine” constitute defamation per se because they tend to injure Dr. Croce in his trade, profession, and occupation.

They falsely impute to Dr. Croce dishonesty, academic corruption, fraud and deceit, in a manner injurious to the reputation and esteem of Dr. Croce professionally.

25. Because Defendant Sanders' statements constitute defamation per se, damages and actual malice are presumed to exist. The defamatory statements also proximately caused Dr. Croce damages in the form of injury to his reputation as a highly respected scientist and cancer researcher.

26. By publishing the false and defamatory statements to a New York Times reporter, Sanders knew and expected that the New York Times reporter would republish them. The New York Times reporter did in fact republished the statements to Dr. Croce's employer in Ohio.

27. The defamatory statements are false, and were false when made. Sanders knew or should have known the statements were false when made.

28. Sanders made the defamatory statements with actual malice and wrongful and willful intent to injure Dr. Croce. The statements were made with knowledge of their falsity or with reckless disregard for their truth or falsity. Sanders knew or should have known that the statements were injurious to Dr. Croce's professional reputation.

29. Sanders never contacted or communicated with or to Dr. Croce prior to publishing his false and defamatory statements about Dr. Croce to Glanz at the New York Times. Dr. Croce does not know, and had never heard of, Sanders prior to receiving the letter that Glanz sent to Dr. Croce and OSU in Ohio.

30. As a proximate result of Sanders's publication of the false and defamatory statements, Dr. Croce has suffered and will continue to suffer damages in an amount to be determined at trial, but in excess of \$25,000.

31. In making the defamatory statements, Sanders acted intentionally, maliciously, willfully and with the intent to injure Dr. Croce and/or to benefit himself.

32. Sanders is liable to Dr. Croce for punitive damages in an amount to be proven at trial.

COUNT II

(Intentional infliction of emotional distress)

33. Plaintiff repeats and incorporates by reference herein each of the preceding paragraphs.

34. Defendant's false and defamatory statements that "image fabrication, duplication and mishandling, and plagiarism in Dr. Croce's papers is routine" and that Dr. Croce is "knowingly engaging in scientific misconduct and fraud" were made intentionally, maliciously, and willfully.

35. Defendant either intended to cause Dr. Croce emotional distress, or knew or should have known that his conduct would result in serious emotional distress.

36. Defendant's conduct, as described herein, was extreme and outrageous, going beyond the bounds of decency. An average member of the community, including of the scientific community, would feel anger and resentment at Defendant's conduct, and would consider the conduct to be outrageous and intolerable.

37. As a further result of Defendant's actions, Dr. Croce has suffered serious mental anguish and personal humiliation, all of a nature that no reasonable person could or should be expected to endure.

WHEREFORE, Plaintiff Carlo M. Croce demands judgment against Defendant David A. Sanders for compensatory damages in an amount to be proven at trial, punitive damages in an amount to be proven at trial, all costs, interest, attorneys' fees and other

amounts permitted by law, and such other and further relief as this Court may deem just and proper.

/s/ Thomas W. Hill
Thomas W. Hill (0012182)
Loriann E. Fuhrer (0068037)
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Attorneys for Plaintiff, Carlo M. Croce, M.D.