



## Final Report of the College of Medicine Investigation Committee Concerning Allegations of Research Misconduct (DIO 7026)

October 8, 2021

### Executive Summary

According to The Ohio State University Policy and Procedures Concerning Research Misconduct ("the Policy"<sup>1</sup>), a College of Medicine Investigation Committee (the "COMIC") conducted a formal Investigation with respect to the allegations of potential Research Misconduct against Michela Garofalo, Ph.D. (the "Respondent"). Dr. Garofalo was a former Visiting Scholar (2006-2008), Post-Doctoral Researcher (2008-2011), and Research Scientist (2011-2014) in the laboratory of Carlo M. Croce, M.D., Professor, Department of Cancer Biology and Genetics, College of Medicine, The Ohio State University (OSU). A series of allegations of possible data Falsification and Plagiarism were raised by Dr. David Sanders, Associate Professor, Department of Biological Sciences, Purdue University, in documents submitted to the University between March 27, 2017, and April 24, 2019. In total, the COMIC reviewed thirteen (13) allegations in nine (9) publications.

The COMIC determined, by a preponderance of the evidence, that of the thirteen (13) allegations reviewed in this Investigation, there is sufficient evidence to make findings of Research Misconduct for eleven (11) allegations (Allegations #1-8, 13-15). The COMIC determined, by a preponderance of the evidence, that there is insufficient evidence to make a finding of Research Misconduct for two (2) allegations (Allegations #12<sup>2</sup> and 16) and that the allegation be dismissed. The allegations related to publications that cite support from the U.S. Public Health Service (PHS) are Allegation # 6 (Plagiarism) and Allegations #13 and #16 (Falsifications). The PHS support is described [below](#). The COMIC recommends that Dr. Garofalo be permanently ineligible for rehire at The Ohio State University and be required to correct or retract Manuscripts #1, #2, #4, #5, and #8 and inform the editors of Manuscript #3, #6, #7 and #9, which already have been corrected, that there are additional issues with these publications.

### Allegation Summary

**Manuscript #1<sup>3</sup>:** Garofalo M, Di Leva G, Romano G, Nuovo G, Suh SS, Ngankeu A, Taccioli C, Pichiorri F, Alder H, Secchiero P, Gasparini P, Gonelli A, Costinean S, Acunzo M, Condorelli G, Croce CM. "miR-221&222 regulate TRAIL resistance and enhance tumorigenicity through PTEN and TIMP3 downregulation." *Cancer Cell*. 2009 Dec 8; 16(6): 498-509.

Manuscript #1, Allegation #1 – Dr. Garofalo plagiarized ten (10) specific instances of text in *Cancer Cell* 2009.

Manuscript #1, Allegation #2 – Dr. Garofalo falsified Figure 1G and/or 1B data, in which the same data were used in *Cancer Cell* 2009, Figure 1G, in lanes 1 and 2 of the beta-actin panel, and in Garofalo et al., *PLoS ONE* 2008, 3(12): e4070. Figure 1B, in lanes 1 and 2 of the beta-actin panel. The same data (different data than in lanes 1 and 2) were also used in *Cancer Cell* 2009, Figure 1G, in lanes 2 and 3 for beta-actin and in Garofalo et al., *PLoS ONE* 2008, Figure 1B, in lanes 1 and 2 for the Akt panel.

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<sup>1</sup> Ex. 001 - University Policy and Procedures Concerning Research Misconduct

<sup>2</sup> The COMIC initially made a research misconduct finding for Allegation 12, but it was changed to no research misconduct after the Respondent responded to the Preliminary Report of the Investigation (see Response to the Preliminary Report section below).

<sup>3</sup> Ex. 012 - Garofalo et al *Cancer Cell* 2009



Manuscript #1, Allegation #3 – Dr. Garofalo falsified Figure 5B and/or 5E, in which the same data were used as the 'Akt tot' panel and as the beta-actin panel in Figure 5B. The same data were also used in Figure 5E as the beta-actin panel (flipped vertically).

Manuscript #1, Allegation #4 – Dr. Garofalo falsified Figure 7D and/or 7F, in which the same data were used in lane 1 of the MET blot (Calu-1) in Figure 7D and used in lane 3 of the MET blot (GTL16) in Figure 7F.

**Manuscript #2<sup>4</sup>:** Garofalo M, Quintavalle C, Romano G, Croce CM, Condorelli G. "miR221/222 in cancer: their role in tumor progression and response to therapy." *Curr Mol Med*. 2012 Jan; 12 (1): 27-33.

Manuscript #2, Allegation #5 – Dr. Garofalo plagiarized fourteen (14) specific instances of text in *Curr Mol Med* 2012.

**Manuscript #3<sup>5</sup>:** Garofalo M, Jeon YJ, Nuovo GJ, Middleton J, Secchiero P, Joshi P, Alder H, Nazaryan N, Di Leva G, Romano G, Crawford M, Nana-Sinkam P, Croce CM. "MiR-34a/c-Dependent PDGFR- $\alpha/\beta$  Downregulation Inhibits Tumorigenesis and Enhances TRAIL-Induced Apoptosis in Lung Cancer." *PLoS One*. 2013 Jun 21; 8 (6): e67581. **Correction-06/25/2015<sup>6,7</sup>**

Manuscript #3, Allegation #6 – Dr. Garofalo plagiarized eleven (11) specific instances of text in *PLoS One* 2013.

**Manuscript #4<sup>8</sup>:** Garofalo M, Croce CM. "MicroRNAs as therapeutic targets in chemoresistance." *Drug Resist Updat*. 2013 Jul-Nov; 16 (3-5): 47-59. Epub 2013 Jun 10.

Manuscript #4, Allegation #7 – Dr. Garofalo plagiarized nine (9) specific instances of text in *Drug Resist Update* 2013.

**Manuscript #5<sup>9</sup>:** Garofalo, M and Croce CM. "microRNAs: Master Regulators as Potential Therapeutics in Cancer." *Annual Review of Pharmacology and Toxicology* 2011 51: 1, 25-43.

Manuscript #5, Allegation #8 – Dr. Garofalo plagiarized three (3) specific instances of text in *Annu Rev Pharm & Tox* 2011.

**Manuscript #6<sup>10</sup>:** Garofalo M, Quintavalle C, Di Leva G, Zanca C, Romano G, Taccioli C, Liu CG, Croce CM, Condorelli G. "MicroRNA signatures of TRAIL resistance in human non-small cell lung cancer." *Oncogene*. 2008 Jun 19; 27 (27): 3845-55. Epub 2008 Feb 4. **Correction-01/04/2021<sup>11, 12</sup>**

Manuscript #6, Allegation #12 – Dr. Garofalo plagiarized one (1) specific instance of text in *Oncogene* 2008.

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<sup>4</sup> Ex. 015 - Garofalo et al *Curr Mol Med* 2012

<sup>5</sup> Ex. 019 - Garofalo et al *PLoS One* 2013

<sup>6</sup> Ex. 020 - Correction-PLOS 2013 Garofalo et al.

<sup>7</sup> The correction addresses six (6) of the eleven (11) instances of plagiarism reviewed in this investigation, as described in the Investigation Committee Analysis section.

<sup>8</sup> Ex. 021 - Garofalo and Croce *Drug Resist Update* 2013

<sup>9</sup> Ex. 033 - Garofalo and Croce *Annu Rev Pharm & Tox* 2011

<sup>10</sup> Ex. 035 - Garofalo et al *Oncogene* 2008

<sup>11</sup> Ex. 761 – Correction-Garofalo et al *Oncogene* 2008

<sup>12</sup> The correction pertains to Figure 4C and 7A only.



Manuscript #6, Allegation #16 – (**see NOTE for Manuscript #10, Allegation #16 below**) – Dr. Garofalo falsified Northern blot data by the reuse of the same data to represent different experimental conditions and treatments as the U6 blot for Figure 3B in Garofalo Oncogene 2008 (Manuscript #6) and the U6 blot for Figure 4C of Garzon PNAS 2008.

**Manuscript #7<sup>13</sup>**: Garofalo M, Romano G, Di Leva G, Gerard Nuovo, Young-Jun Jeon, Apollinaire Nkankeu, Jin Sun, Francesca Lovat, Hansjuerg Alder, Gerolama Condorelli, Jeffrey A Engelman, Mayumi Ono, Jin Kyung Rho, Luciano Cascione, Stefano Volinia, Kenneth P Nephew & Carlo M Croce. EGFR and MET receptor tyrosine kinase-altered microRNA expression induces tumorigenesis and gefitinib resistance in lung cancers. Nature Medicine. 2012;18(1):74-82. doi:10.1038/nm.2577. **Correction: 11/19/13<sup>14, 15</sup>**

Manuscript #7, Allegation #13 – Dr. Garofalo falsified Figure 1B, in which the same data were used in the shEGFR panel (lines miR-30c to MiR-101) and the shMET panel (lines miR-548d to miR-203).

**Manuscript #8<sup>16</sup>**: Calore, F, Lovat, F and Garofalo, M. Non-Coding RNAs and Cancer. Int J Mol Sci. Aug 2013; 14(8): 17085–17110.

Manuscript #8, Allegation #14 – Dr. Garofalo plagiarized sixteen (16) specific instances of text in Int J Mol 2013.

**Manuscript #9<sup>17</sup>**: Jeon YJ, Middleton J, Kim T, Laganà A, Piovan C, Secchiero P, Nuovo GJ, Cui R, Joshi P, Romano G, Di Leva G, Lee BK, Sun HL, Kim Y, Fadda P, Alder H, Garofalo M, Croce CM. "A set of NF-κB-regulated microRNAs induces acquired TRAIL resistance in lung cancer." Proc Natl Acad Sci U S A. 2015 Jun 30;112(26):E3355-64. Epub 2015 Jun 15. **Corrected – 03/21/2017<sup>18, 19</sup>**

Manuscript #9, Allegation #15 - Dr. Garofalo plagiarized sixteen (16) instances of text in Jeon et al., **PNAS 2015**.

**NOTE: Manuscript #10, PNAS** is listed here for consistency, since it appears in the notification to Dr. Garofalo.<sup>20</sup> Allegation #16 involves figures in both PNAS 2008 and Oncogene 2008. However, due to the time limitations regarding PNAS 2008,<sup>21</sup> this allegation (#16) is reviewed under Oncogene 2006 (Manuscript #6).

**Manuscript #10<sup>22</sup>**: Garzon R\*, Garofalo M\*, Martelli MP, Briesewitz R, Wang L, Fernandez-Cymering C, Volinia S, Liu CG, Schnittger S, Haferlach T, Liso A, Diverio D, Mancini M, Meloni G, Foa R, Martelli MF, Mecucci C, Croce CM, Falini B. "Distinctive microRNA signature of acute myeloid leukemia bearing cytoplasmic mutated nucleophosmin." PNAS. 2008 Mar 11;105(10):3945-50. doi: 10.1073/pnas.0800135105. Epub 2008 Feb 28. **\*Co-first author**

<sup>13</sup> Ex. 458 - Garofalo Nature Medicine 2012

<sup>14</sup> Ex. 497 - Correction Garofalo et al Nature Medicine 2012

<sup>15</sup> The correction pertains to Figures 1a and 6g only.

<sup>16</sup> Ex. 462 - Calore Int J Mol Sci 2013

<sup>17</sup> Ex. 027 - Jeon et al PNAS 2015

<sup>18</sup> Ex. 028 – Correction PNAS-2015-Jeon

<sup>19</sup>The correction addressed six (6) of the sixteen (16) instances of plagiarism reviewed in this investigation, as described in the Investigation Committee Analysis section.

<sup>20</sup> Ex. 631 - 20190828 - Notification of Allegations\_Garofalo

<sup>21</sup> Garzon PNAS 2008 was designated as Manuscript #10 in the Notification of Allegations on 08/28/2019, in the interview transcripts and in the PowerPoint Forensic file. Dr. Garofalo is a co-first author on Garzon PNAS 2008. It was later identified that PNAS 2008 was beyond the six-year time limitation as defined in 42 C.F.R. 93.105(a) and there was no subsequent use exception for Dr. Garofalo.

<sup>22</sup> Ex. 598 - Garzon PNAS 2008



Manuscript #10, Allegation #16 - The same Northern blot data were reused to represent different experimental conditions and treatments as the U6 blot for Figure 3B of Garofalo Oncogene 2008 Jun 19; 27 (27): 3845-55. Epub 2008 Feb 4 (Manuscript #6) and the U6 blot for Figure 4C of Garzon PNAS 2008.

### **Subsequent Use Summary**

Five (5) of the questioned publications reviewed in this Investigation were beyond the six-year time limitation as defined in C.F.R. §93.105(a) and the Policy, Section V.I. Therefore, the publications were reviewed under the subsequent use exception process.<sup>23</sup> The Office of Research Compliance (ORC) determined that the six-year time limitation did not apply to these manuscripts because Dr. Garofalo cited the questioned publications as follows:

#### Manuscript #1: Cancer Cell 2009

- Cited in Michela Garofalo, Giulia Romano, Gianpiero Di Leva, Gerard Nuovo, Young-Jun Jeon, Apollinaire Ngankeu, Jin Sun, Francesca Lovat, Hansjuerg Alder, Gerolama Condorelli, Jeffrey A Engelman, Mayumi Ono, Jin Kyung Rho, Luciano Cascione, Stefano Volinia, Kenneth P Nephew & Carlo M Croce "EGFR and MET receptor tyrosine kinase–altered microRNA expression induces tumorigenesis and gefitinib resistance in lung cancers." Nature Medicine volume 18, pages 74–82 (2012)

#### Manuscript #5: Annu Rev Pharm & Tox 2011

- Cited in Gerard J Nuovo, Michela Garofalo, Nicola Valeri, Vicki Roulstone, Stefano Volinia, David E Cohn, Mitch Phelps, Kevin J Harrington, Richard Vile, Alan Melcher, Evanthia Galanis, Sarah Sehl, Rob Adair, Karen Scott, Ailsa Rose, Giles Toogood & Matthew C Coffey. "Reovirus-associated reduction of microRNA-let-7d is related to the increased apoptotic death of cancer cells in clinical samples." Modern Pathology volume 25, pages 1333–1344 (2012)

#### Manuscript #6: Oncogene 2008

- Cited in Garofalo M, Quintavalle C, Romano G, Croce CM, Condorelli G. "miR221/222 in cancer: their role in tumor progression and response to therapy." Curr Mol Med. 2012 Jan; 12 (1): 27-33.

#### Manuscript #7: Nature Medicine 2012

- Cited in Di Leva G, Garofalo M, Croce CM. "MicroRNAs in cancer." Annu Rev Pathol. 2014; 9:287-314. Epub 2013 Sep 25.
- Cited in Garofalo M, Croce CM. "MicroRNAs as therapeutic targets in chemoresistance." Drug Resist Updat. 2013 Jul-Nov; 16 (3-5): 47-59. Epub 2013 Jun 10.

#### Manuscript #10: PNAS 2008/Oncogene 2008

- Dr. Garofalo is a co-first author on PNAS 2008 as well as first author on Oncogene 2008, and Oncogene 2008 (Manuscript #6) was subsequently cited. Therefore, the reuse of the allegedly falsified data in Oncogene 2008 and PNAS 2008 brings the allegation #16 into OSU jurisdiction for investigation.

### **Preliminary Assessment Summary**

On June 19, 2017, Robert A. Bornstein, Ph.D., former Vice Dean for Academic Affairs, Administrative Vice Dean, met with David Wright, Ph.D., External, Independent Research Integrity Officer (RIO), and Julia

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<sup>23</sup> Ex. 002 - Subsequent Use Exception Process-V1



Behnfeldt, Ph.D., former OSU RIO, Associate Director, ORC, to review the allegations<sup>24</sup> and conduct a Preliminary Assessment (PA) under the Policy.

On August 17, 2017, the Preliminary Assessment letter<sup>25,26</sup> for the allegations of possible Research Misconduct was submitted to the Deciding Official in this matter, Karla Zadnik, O.D., Ph.D., Dean and Glenn A. Fry Professor in Optometry and Physiological Optics, OSU, and recommended that this case be moved forward to a Committee of Initial Inquiry (CII). On August 22, 2017, Dr. Zadnik concurred with the PA and indicated that a CII should be initiated.<sup>27</sup>

### **Sequestration of Data Summary**

Prior to Dr. Garofalo's notification on November 7, 2017,<sup>28</sup> data relating to the allegations were sequestered from the laboratory of her former advisor, Dr. Carlo Croce, on July 20, 2017. A box of original records with the labeling of "Michela Garofalo" was sequestered (notebooks, lab books, steno pads – see "CMC-4"<sup>29</sup>) and stored securely in ORC.

### **Committee of Initial Inquiry Summary**

The CII was formed on August 23, 2017 (with members charged on August 23, 2017, October 10, 2017, and January 17, 2018) to review the allegations of possible Research Misconduct made against Dr. Garofalo. On January 2, 2019, the CII issued its Preliminary Report.<sup>30</sup> Dr. Garofalo was given an extension until February 18, 2019, to provide her comments.<sup>31</sup> Dr. Garofalo provided her written comments to the CII on February 15, 2019.<sup>32</sup>

On January 2, 2019, Dr. David Sanders, Complainant, was provided with a redacted version of the CII's Preliminary Report and given two weeks (due January 17, 2019) in which to review and provide comments to the Preliminary Report in accordance with Policy Section IV.C.4. Due to the size and scope of the Preliminary Report,<sup>33</sup> Dr. Sanders was given an extension until February 18, 2019 in order to provide his comments.<sup>34</sup> Dr. Sanders requested and was provided with an additional week extension to provide his comments.<sup>35</sup> On February 25, 2019, Dr. Sanders provided his written response to the Preliminary Report, which included additional allegations for potential falsification of figures and/or plagiarism involving two new publications and one publication (Manuscript #6) already under review.<sup>36,37,38</sup>

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<sup>24</sup> Ex. 081c - PA Exhibit 3 - Allegations to CII\_redacted Garofalo

<sup>25</sup> Ex. 080a - 20170822 Croce Preliminary Assessment Revised 2\_redacted

<sup>26</sup> Ex. 081c - PA Exhibit 3 - Allegations to CII\_redacted Garofalo

<sup>27</sup> Ex. 084a - 20170822- DO to RIO Croce PA Agreement\_Redacted

<sup>28</sup> Ex. 092 - 20171107- Garofalo Notification

<sup>29</sup> Ex. 107b - 20170720 Data Sequestration Sheet\_redacted Garofalo

<sup>30</sup> Ex. 318 - 20190102 - Garofalo CII Preliminary Report

<sup>31</sup> Ex. 338 - 20190107- Email RIO to Garofalo- deadline extended

<sup>32</sup> Ex. 384 - Response to the CII report MG

<sup>33</sup> The Preliminary Report included the parent report, which included the allegations for Dr. Garofalo as well as the review of several other allegations that were reviewed separately by the university.

<sup>34</sup> Ex. 349 - 20190107- Email RIO to Sanders- deadline extended

<sup>35</sup> Ex. 385 - 20190218- Email RIO to Sanders Counsel-Extension

<sup>36</sup> Ex. 448 - 20190225 - Sanders response to PR - Garofalo Response

<sup>37</sup> Ex. 449 - 20190225 - Sanders response to PR - Garofalo - EGFR and MET...

<sup>38</sup> Ex. 450 - 20190225 - Sanders response to PR - Garofalo - Non-Coding RNAs and Cancer





On May 17, 2019, the CII issued its Final Report,<sup>39</sup> which determined that there was sufficient substantive evidence that Research Misconduct may have occurred to warrant further Investigation of Dr. Garofalo under the University's Policy and disciplinary process. On June 25, 2019, the Deciding Official, Dr. Karla Zadnik, concurred with the CII determination.<sup>40, 41</sup> On June 27, 2019, the decision to initiate an investigation was referred to the Office of Human Resources where the Investigation would be conducted pursuant to the University Policy and the Office of Human Resources policies.<sup>42, 43</sup>

### **College of Medicine Investigation Committee**

After screening each potential member for the College of Medicine Investigation Committee (the "COMIC") to ensure that they were free from any possible conflict of interest that would prevent a fair and impartial review of the allegations, the COMIC members were charged on July 8 and July 22, 2019, to (1) examine all evidence and collect any additional evidence it deemed appropriate; (2) determine if the allegations constitute Research Misconduct (i.e., meets all of the criteria required for a finding of Research Misconduct as outlined in the Policy Section III.A), and if so, whether Dr. Garofalo is responsible for the Research Misconduct; and (3) recommend sanctions if the COMIC determines that Dr. Garofalo committed Research Misconduct.

To ensure that the Investigation was conducted with the appropriate scientific domain experience and expertise, the investigation committee was comprised of faculty from the College of Medicine to determine if Research Misconduct had occurred. A member of the College of Medicine's Human Resources (COM HR) staff was appointed to the College of Medicine Investigation Committee to consider the interests of Dr. Garofalo as a staff member.

The composition of the COMIC was as follows:

- Arthur Burghes, Ph.D. (**Chair**), Professor, Department of Biological Chemistry and Pharmacology, College of Medicine
- Brandon Biesiadecki, Ph.D., Associate Professor, Department of Physiology & Cell Biology, College of Medicine
- Jonathan Davis, Ph.D., Professor, Department of Physiology and Cell Biology, College of Medicine
- Jill A. Rafael-Fortney, Ph.D., Professor, Department of Physiology & Cell Biology, Biological Chemistry & Pharmacology, College of Medicine
- Yutong Zhao, M.D., Ph.D., Professor, Department of Physiology and Cell Biology, College of Medicine
- Thomas Hund, Ph.D. (**non-COM representative**), Professor, Department of Biomedical Engineering, College of Engineering
- Loren Wold, Ph.D. (**non-COM representative**), Professor, Colleges of Nursing and Medicine (Physiology and Cell Biology)
- Colleen Rupp (**COM HR representative**), Senior Employee and Labor Relations Consultant, Wexner Medical Center Human Resources

### **College of Medicine Investigation Committee Meetings**

- 07/08/19: COMIC charging meeting with Drs. Wold, Burghes, Rafael-Fortney, Zhao, and Hund and Ms. Rupp. Dr. Behnfeldt and Ms. Mankowski from ORC and Ms. Emily Schriver from the Office of Legal

<sup>39</sup> Ex. 574a - 20190517 - Garofalo CII Final Report

<sup>40</sup> Ex. 608 - 20190625- Letter DO to Garofalo- DO Decision

<sup>41</sup> Ex. 609 - 20190625- Email RIO to Garofalo- DO Decision

<sup>42</sup> Ex. 610 - 20190627 - Letter Chair CII to HR-Garofalo

<sup>43</sup> Ex. 611 - 20190627-Email ORC to Garofalo\_Referral of Investigation



Affairs, discussed the University Policy and Procedures Concerning Research Misconduct and process and the specific charge of the COMIC.

- 07/22/19: COMIC charging meeting with Drs. Biesiadecki and Davis
- 08/05/19: COMIC working meeting. Dr. Burghes was chosen as the committee chair.
- 08/05/19: COMIC working meeting
- 08/19/19: COMIC working meeting
- 08/26/19: COMIC working meeting
- 09/09/19: COMIC working meeting
- 09/23/19: COMIC working meeting
- 10/07/19: COMIC working meeting
- 10/14/19: COMIC only members working meeting
- 10/21/19: COMIC working meeting
- 10/31/19: COMIC interview of Respondent, Dr. Michela Garofalo<sup>44</sup>
- 10/31/19: COMIC interview of Complainant, Dr. David Sanders
- 11/04/19: COMIC working meeting
- 11/15/19: COMIC interview of Witness, Dr. Ramiro Garzon
- 11/19/19: COMIC interview of Witness, Dr. Carlo Croce
- 12/02/19: COMIC voting meeting
- 12/09/19: COMIC voting meeting
- 01/06/20: COMIC voting meeting
- 01/13/20: COMIC voting meeting
- 04/06/20: COMIC working meeting
- 08/31/20: COMIC working meeting
- 09/24/21: COMIC voting meeting

### **Research Records and Evidence/Written Responses from Respondent**

Dr. Garofalo provided several responses during the Research Misconduct proceedings. The responses provided during the Inquiry and Investigation, and referred to in the analyses of the allegations below, are:

- 1) A written response to the CII on November 21, 2017,<sup>45</sup> with 14 attachments.<sup>46, 47</sup>
- 2) A written response to the CII Preliminary Report on February 15, 2019.<sup>48</sup>
- 3) A written response to the amendment of the CII Preliminary Report on May 10, 2019.<sup>49</sup>
- 4) Written email responses to new allegations related to Nature Medicine 2012 on April 2, 2019<sup>50</sup> and April 12, 2019.<sup>51</sup>
- 5) A written response to new allegations related to Oncogene 2008 and PNAS 2008 on September 12, 2019, with two attachments.<sup>52</sup>

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<sup>44</sup> The forensic documents referenced during Dr. Garofalo's interview were Ex. 659 - COMIC Figure Forensics-Garofalo -20190828 updated and Ex. 661 - COMIC Plagiarism Forensics - Garofalo

<sup>45</sup> Dr. Garofalo sent a response on 11/20/17, and a follow up on 11/21/17 to indicate she attached the wrong file in her 11/20/17 response ("Response to the allegation" on 11/20; "Response to the allegation MG" on 11/21). This report will use the response date of 11/21/17.

<sup>46</sup> Ex. 150 - Response to the allegations MG

<sup>47</sup> Ex. 657 - FOLDER: 20171120 Garofalo Response

<sup>48</sup> Ex. 384 - Response to the CII report MG

<sup>49</sup> Ex. 568 - response to amendment of CII report

<sup>50</sup> Ex. 489 - 20190402- Garofalo Response to Allegations

<sup>51</sup> Ex. 510 - 20190412 Garofalo Response to the Allegations

<sup>52</sup> Ex. 639 - Garofalo Oncogene-PNAS U6 (with attachments)

- 6) A written response following the COMIC interview on December 2, 2019.<sup>53</sup>

### **Notification of Additional Allegations**

During the Inquiry, the CII identified additional information implicating Dr. Garofalo's possible involvement in Plagiarism regarding Jeon et al., PNAS 2015 (Manuscript #9, Allegation #15) that had not been under review for Dr. Garofalo.<sup>54</sup> By a majority vote, the CII recommended, and included in the CII Final Report, that the manuscript be reviewed by the Investigation Committee with Dr. Garofalo as a Respondent.

Additional concerns were submitted by Dr. David Sanders on April 9, 2019.<sup>55,56</sup> The CII examined the new allegations but recommended that these allegations be reviewed by the COMIC during the investigation to determine if they were specific and credible allegations of Research Misconduct. The COMIC determined by a majority vote that one (1) allegation (Allegation #16) was specific and credible and may indicate possible Research Misconduct as defined in Section III of the Policy. Therefore, the one (1) allegation was added to the scope of the Investigation. Dr. Garofalo was notified of the additional allegation on August 28, 2019.<sup>57,58, 59</sup> In the notification, Dr. Garofalo was asked to submit any data related to the allegation by September 13, 2019. On September 12, 2019, Dr. Garofalo provided<sup>60</sup> via email a written response to the allegation,<sup>61</sup> an enlarged image of the figures in question in which Dr. Garofalo points out what she claims to be differences in the images,<sup>62</sup> and the purported original data for Figure 3B of Garofalo Oncogene 2008.<sup>63</sup>

### **Interview/s Summary**

Dr. Garofalo was interviewed by the COMIC on October 31, 2019.<sup>64</sup> During the interview, Dr. Garofalo was shown PowerPoint presentations<sup>65, 66</sup> summarizing the allegations under investigation. Dr. Garzon was interviewed by the COMIC on November 15, 2019,<sup>67</sup> Dr. Croce was interviewed by the COMIC on November 19, 2019,<sup>68</sup> and Dr. David Sanders, the Complainant, was interviewed by the COMIC on October 31, 2019.<sup>69</sup> Specific responses to the allegations are included in the [Investigation Committee Analysis](#) below.

### **Criteria Required for a Finding of RM**

Per the Policy, Section III.A., Research Misconduct means Fabrication, Falsification or Plagiarism in proposing, performing, or reviewing research, or in reporting research results. The allegations reviewed in this Investigation Report are the Falsification of data. Falsification is defined as:

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<sup>53</sup> Ex. 674 - 20191202 - Garofalo Response - To the Committee

<sup>54</sup> Ex. 027 - Jeon et al PNAS 2015

<sup>55</sup> Ex. 492 - 20190409 – Email Sanders to RIO PR summary

<sup>56</sup> Ex. 491b - AllSum22519 response\_Redacted-Garofalo

<sup>57</sup> Ex. 631 - 20190828 - Notification of Allegations\_Garofalo. The notification includes Allegation #16 in PNAS 2008 as Manuscript #10 as describe above, but was reviewed during the investigation under Oncogene 2008 (Manuscript #6).

<sup>58</sup> Ex. 632 - 20190828 - Notification of Allegations\_Garofalo Figures

<sup>59</sup> Ex. 633 - 20190828- Email RIO to Garofalo\_Notification

<sup>60</sup> Ex. 638 - 20190912-Email Garofalo to RIO\_Response to Allegations

<sup>61</sup> Ex. 639 - Garofalo Oncogene-PNAS U6

<sup>62</sup> Ex. 641 - U6-Oncogene-PNAS

<sup>63</sup> Ex. 640 - GarofaloetalFig3

<sup>64</sup> Ex. 658 - 20191031 - COMIC Interview + errata - Garofalo

<sup>65</sup> Ex. 659 - COMIC Figure Forensics-Garofalo -20190828 updated

<sup>66</sup> Ex. 661 - COMIC Plagiarism Forensics - Garofalo

<sup>67</sup> Ex. 698a – 20191115 – COMIC interview + Errata – Garzon\_Redacted-Garofalo

<sup>68</sup> Ex. 710d - 20191119 - COMIC Interview + errata – Croce-Garofalo\_Redacted

<sup>69</sup> Ex. 645d - 20191031 - COMIC Interview + errata – Sanders\_Redacted Garofalo





Section III.F: Falsification. "Falsification" is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.

In the "Investigation Committee Analysis" section below, the COMIC used forensic analysis to determine which of the questioned figures have been falsified by the reuse of the same blot to represent different experimental conditions and proteins. In most instances, the Respondent does not dispute the duplication of data. Additionally, in some instances, the Plagiarism was supported by the fact that corrections were published for Manuscripts #3 and #9.

The allegations reviewed in this Investigation Report also include Plagiarism. Plagiarism is defined as:

Section III.G: Plagiarism. "Plagiarism" is the appropriation of the ideas, processes, results, or words of another person, without giving appropriate credit.

In the "Investigation Committee Analysis" section below, the COMIC reviewed each instance of alleged Plagiarism to determine if the text was copied verbatim, if the text was appropriately cited, and evaluated the significance of the totality of the Plagiarism.

Per the Policy, Section III.A.1, a finding of Research Misconduct requires:

- A. That there be a significant departure from the accepted practices of the relevant research community; and
- B. The misconduct be committed intentionally, knowingly, or recklessly; and
- C. The allegation be proved by a Preponderance of the Evidence.

**Analysis of criteria A:** "That there be a significant departure from the accepted practices of the relevant research community." The COMIC determined that the relevant research community for this Investigation would be experienced biomedical researchers using molecular biology, biochemical and molecular genetic techniques in an academic setting with experience in publishing and grant writing. The COMIC members, with the exception of the HR staff representative, all represent this community with their experience and status as either associate or full professors with experience in molecular biology research with numerous grants and publications. Specifically, the COMIC faculty members have each been in various positions required in the academic pathway to become a faculty member who oversees trainees, including being a graduate student followed by post-doctoral researcher training. At each stage of their careers, the COMIC members have participated in Responsible Conduct of Research (RCR) training and have a firsthand understanding of the knowledge, independence and responsibilities of a trainee at each level. As a collective, the COMIC has trained 30+ post-doctoral researchers and 29+ graduate students. Three COMIC members have been directly involved in the formal teaching of RCR in university courses required for trainees including, but not limited to, topics on professional ethics, proper figure generation, data analysis and plagiarism. Further, all of the COMIC members train their own mentees and lab members on accepted practices and RCR. Therefore, their assessment of what is an accepted practice is based on their collective knowledge of and active participation in the relevant academic biomedical research community.

**Analysis of criteria B:** "The misconduct be committed intentionally, knowingly, or recklessly." The definitions of "intentionally, knowingly, or recklessly" are not listed in the Policy, nor in the federal



regulations (42 C.F.R § 93) applicable in this Investigation. Based on federal, state, and university guidance, the COMIC used the following definitions for this investigation:

**Intentionally:** Respondent directly engages in Fabrication, Falsification or Plagiarism with the intent, or purpose, of misleading the readers of the research record.

**Knowingly:** Respondent has actual knowledge of the Fabrication, Falsification or Plagiarism or acts in deliberate ignorance or plain indifference of the Fabrication, Falsification or Plagiarism.

**Recklessly:** Respondent is on notice of a significant increased risk of falsified, fabricated, or plagiarized data and/or text being used or generated, or the risk is so obvious that a typical researcher in the relevant research community should have known, and through action or inaction, the respondent uses, or allows the use of, the falsified, fabricated, or plagiarized data and/or text.

**Analysis of criteria C:** "The allegation be proved by a Preponderance of the Evidence". The preponderance of the evidence standard comes from the federal regulations under CFR 93.104 (c) and the University Policy Section III.H., which states:

"Preponderance of the Evidence" means proof by information that, compared with that opposing it, leads to the conclusion that the fact at issue is more probably true than not.

The COMIC generally will interpret preponderance of the evidence to mean at a certainty of greater than 50%.

Per the Policy Section III.A.2, Research Misconduct specifically does not include honest error or differences of opinion. As stated in 42 CFR 93.106(b)(2), the Respondent has the burden of proving, by a preponderance of the evidence, any affirmative defense or honest error. The COMIC must determine whether any claim of honest error or an affirmative defense is proven by the preponderance of the evidence.

### **Investigation Committee Analysis**

The specific allegations against Dr. Garofalo are reviewed by the COMIC below. The forensic analysis for the questioned figures is included with this report as "COMIC Figure Forensics – Garofalo\_FINAL"<sup>70</sup> and the forensic analysis for the questioned plagiarized text is included with this report as "COMIC Plagiarism Forensics – Garofalo."<sup>71</sup>

### **Respondent Responses Regarding Plagiarism**

During the CII interview on March 2, 2018, and the COMIC interview on October 31, 2019, Dr. Garofalo was asked about Plagiarism and her responses below are relevant to all allegations of Plagiarism (Allegations #1, 5, 6, 7, 8, 12, 14, and 15). The following summarizes Dr. Garofalo's responses to the CII and the COMIC regarding Plagiarism:

1. In her written response to the initial allegations, provided to the CII on November 21, 2017, Dr. Garofalo indicated that she did not "*steal any intellectual properties since the reported sentences refer to previously published scientific finding.*"<sup>72</sup>

<sup>70</sup> Ex. 660 - COMIC Figure Forensics-Garofalo\_FINAL

<sup>71</sup> Ex. 661 - COMIC Plagiarism Forensics - Garofalo

<sup>72</sup> Ex. 150 - Response to the allegations MG, page 2



2. In the interview with the CII on March 2, 2018, Dr. Garofalo indicated that she was not aware that Plagiarism meant copying words/text, but rather that it meant copying the ideas and findings of others and claiming them as one's own.<sup>73</sup>
3. In the CII interview, Dr. Garofalo said that the material in question is very technical and she did not know how to change it without misleading the reader.<sup>74</sup>
4. In the CII interview, Dr. Garofalo indicated that she had not understood the meaning of Plagiarism until the allegations were raised in 2015, after which she began to analyze her work with Turnitin software.<sup>75</sup>
5. In the CII interview, Dr. Garofalo stated that she had a lack of training in what constitutes Plagiarism,<sup>76</sup> that there was a lack of oversight in the Croce lab<sup>77</sup> since Dr. Croce was always traveling and never in the lab,<sup>78</sup> and that Dr. Croce simply read the articles and changed very little - such as punctuation.<sup>79</sup>
6. In her response to the CII Preliminary Report, provided to her on February 15, 2019, Dr. Garofalo stated that she did not receive any training on what constitutes plagiarism during her time at OSU in Dr. Croce's laboratory nor did she receive training in her "*country of origin (Italy)*."<sup>80</sup>
7. In the COMIC interview on October 31, 2019, when asked about her definition of Plagiarism, Dr. Garofalo cited the Office of Research Integrity (ORI) Policy on Plagiarism and said her belief is that text intended to mislead the reader about the contribution of the author constitutes Plagiarism. Dr. Garofalo stated that all of the allegations of Plagiarism against her are related to previous research and she was unaware that describing previous research, which is common knowledge, was considered Plagiarism.<sup>81</sup>
8. In the COMIC interview, Dr. Garofalo distinguished theft of ideas as different from copying facts that are common knowledge.<sup>82</sup>
9. In the COMIC interview, Dr. Garofalo said that her current knowledge about Plagiarism is different than what she knew ten years ago, since she had never had any training on Plagiarism or on ethical writing of a manuscript or review article.<sup>83</sup> Dr. Garofalo said that she now knows that even a single sentence copied should cite the paper from which the sentence was copied. Previously, when she worked in the Croce lab, Dr. Garofalo thought it was proper to cite the original source of the work to properly acknowledge who did the work, and not the paper/review from which the text was copied.<sup>84</sup>
10. In the COMIC interview, Dr. Garofalo said that while she was in the Croce lab, she wrote the manuscripts, review articles, and other documents, and in 2014 she joined her current institution, The University of Manchester, Manchester, England. The first allegation of plagiarism was brought to her attention in 2015 regarding the Cancer Cell 2009 paper. Dr. Garofalo said that prior to 2015, she did not know anything about Plagiarism or the proper use of quotation marks if sentences were copied regarding common knowledge or previous research or methodology.<sup>85</sup>

### **Witness Response(s)**

Dr. Croce was interviewed by the COMIC on November 19, 2019.<sup>86</sup> Dr. Croce's responses regarding Plagiarism are relevant to Allegations #1, 5, 6, 7, 8, 12, 14, and 15. Dr. Croce's responses about images are relevant to Allegations # 2, 3, 4, 13, 16. The following summarizes Dr. Croce's responses:

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<sup>73</sup> Ex. 119 - 20180302-CII Interview + errata –Garofalo, page 49, lines 6-9

<sup>74</sup> Ex. 119 - 20180302-CII Interview + errata –Garofalo, page 55 lines 5-12

<sup>75</sup> Ex. 119 - 20180302-CII Interview + errata –Garofalo, page 58, lines 17-24, and page 59, lines 1-5

<sup>76</sup> Ex. 119 - 20180302-CII Interview + errata –Garofalo, page 56, lines 22-23, and page 57, lines 1-2

<sup>77</sup> Ex. 119 - 20180302-CII Interview + errata –Garofalo , page 9 lines 21-24 and page 10 lines 1-12

<sup>78</sup> Ex. 119 - 20180302-CII Interview + errata –Garofalo , page 60 lines 6-19

<sup>79</sup> Ex. 119 - 20180302-CII Interview + errata –Garofalo , page 59 lines 8-16

<sup>80</sup> Ex. 384 – Response to the CII report MG

<sup>81</sup> Ex. 658 - 20191031 - COMIC Interview + errata - Garofalo, p. 4, lines 18-23

<sup>82</sup> Ex. 658 - 20191031 - COMIC Interview + errata - Garofalo, p. 9, lines 1-25

<sup>83</sup> Ex. 658 - 20191031 - COMIC Interview + errata - Garofalo, p. 5, lines 1-5

<sup>84</sup> Ex. 658 - 20191031 - COMIC Interview + errata - Garofalo, p.6, lines 12-20

<sup>85</sup> Ex. 658 - 20191031 - COMIC Interview + errata - Garofalo, p. 15, line 18-23 and p. 16 lines 9-25

<sup>86</sup> Ex. 710d - 20191119 COMIC interview + errata – Croce-Garofalo\_Redacted



1. Dr. Croce said that his understanding of Plagiarism was that the repetition of something in some other paper is Plagiarism.<sup>87</sup>
2. Dr. Croce was questioned on his statements during the Inquiry interview where he had said that plagiarism is when text was copied, but if the text referenced the original article(s), it was not an intent to steal and, therefore, was less serious. Dr. Croce clarified his previous statements and told the COMIC that he believed that if you take even one sentence from another paper that is identical, it is Plagiarism and should not be tolerated.<sup>88</sup>
3. Dr. Croce said he tried to explain to the Inquiry committee that he believed his postdoctoral fellows thought that copying the text was acceptable if the reference to the original work was included. Dr. Croce said that he believed the postdoctoral fellows did not intend to steal anyone's work or ideas.<sup>89</sup>
4. Dr. Croce said that just by reading the paper, he would not have been able to tell if the text was copied from elsewhere (p. 97, lines 2-4).<sup>90</sup>
5. Dr. Croce said that he had made the postdoctoral fellows and students aware of the importance of Plagiarism and not to plagiarize text.<sup>91</sup>
6. When questioned about a number of postdoctoral fellows who claimed in their interviews that they had no idea that copying text was Plagiarism, Dr. Croce said that there was adequate training, his lab staff knew that they should not copy verbatim text, and he told them this multiple times.<sup>92</sup>
7. Dr. Croce said when he received a complaint about a published paper, he would review it with the postdoctoral fellow involved in the study to determine whether the allegation seemed right and if so, whether a correction was needed. Dr. Croce also acknowledged that a mistake can be made by anyone.<sup>93</sup>
8. When questioned about the blots the COMIC had seen during the investigation that were unlabeled and undated, and how he could assess the validity of such blots, Dr. Croce said that when he reviewed the blots they were correctly labeled.<sup>94</sup>
9. Dr. Croce said that he had a large lab with many postdoctoral fellows, and he was not aware of any problem with the work of Dr. Garofalo. Dr. Croce said when he dealt with Dr. Garofalo, he believed in her work, and this was supported because no one else in the lab had come to him with any issues about Dr. Garofalo's work.<sup>95</sup>

### **Summary of the COMIC Conclusions on Plagiarism**

The COMIC carefully reviewed the questioned papers, the Plagiarism forensic files, the interviews, and the documentation from the Respondent provided during the Inquiry and Investigation. The issues of Plagiarism are reviewed separately below for each manuscript. The COMIC's conclusions regarding Plagiarism were strongly influenced by the total amount of textual copying in this case. The COMIC felt that each instance of Plagiarism in each manuscript could not be viewed on its own, except to show in each individual instance that there was copying of text from an unattributed source. The COMIC believed that the total amount of copying in the eight manuscripts under investigation rose to a level of significant Plagiarism. The [Summary of the Investigation Committee Conclusions](#) reflect this, where finding #1 combines the Plagiarism findings. The COMIC found that in some instances, a citation was included in Dr. Garofalo's paper for the original finding; however, it was a citation that also appeared in the source document from which the text was copied. The COMIC believes that Dr. Garofalo simply copied the text from the source document along with the references

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<sup>87</sup> Ex. 710d – 20191119 – COMIC interview + Errata – Croce-Garofalo\_Redacted, p.95, lines 1-3

<sup>88</sup> Ex. 710d – 20191119 – COMIC interview + Errata – Croce-Garofalo\_Redacted, p.95, lines 6-20

<sup>89</sup> Ex. 710d – 20191119 – COMIC interview + Errata – Croce-Garofalo\_Redacted, pgs. 95-96

<sup>90</sup> Ex. 710d – 20191119 – COMIC interview + Errata – Croce-Garofalo\_Redacted, p.97, lines 2-4

<sup>91</sup> Ex. 710d – 20191119 – COMIC interview + Errata – Croce-Garofalo\_Redacted, pgs. 100-101

<sup>92</sup> Ex. 710d – 20191119 – COMIC interview + Errata – Croce-Garofalo\_Redacted, pgs. 100-101

<sup>93</sup> Ex. 710d – 20191119 – COMIC interview + Errata – Croce-Garofalo\_Redacted, p.36, lines 18-24; p.37, lines 16-21

<sup>94</sup> Ex. 710d – 20191119 – COMIC interview + Errata – Croce-Garofalo\_Redacted, p.13, lines 7-17

<sup>95</sup> Ex. 710d – 20191119 – COMIC interview + Errata – Croce-Garofalo\_Redacted, p.81, lines 8-21



cited in the source. Further, the COMIC is aware of the Office of Research Integrity's (ORI) policy, which states that "ORI generally does not pursue [as Plagiarism] the limited use of identical or nearly-identical phrases which describe a commonly-used methodology or previous research".<sup>96</sup> However, the COMIC felt that, in total, this matter involved more than a "limited use" of copied text and ORI's policy would not exclude the significant use of copied text in multiple papers over six (6) years.

In the responses from Dr. Garofalo throughout the Research Misconduct proceedings, Dr. Garofalo reiterated that the textual overlap was not intentional and that she had no training or guidance in Plagiarism while she was working in the Croce laboratory. Specifically, the Plagiarism all resulted from honest error. The COMIC did not find this to be a credible defense and believed that Dr. Garofalo was responsible for the Plagiarism. The COMIC does not believe that someone at Dr. Garofalo's level, working in the Croce laboratory as a Visiting Scholar (2006-2008), a Post-Doctoral Researcher (2008-2011), and a Research Scientist (2011-2014), would not know the meaning of Plagiarism since the concepts of Plagiarism are generally taught early on in one's scientific career. Even with an assumption that Dr. Garofalo might not have been taught as a child that copying text was wrong, the COMIC believes that anyone at a graduate student level or higher should know the meaning of Plagiarism. The COMIC also determined that Dr. Garofalo is the first author on 7 of the 8 manuscripts under investigation for Plagiarism and senior author on one, and she is the only common author on all the papers, except for Dr. Croce.<sup>97</sup> The COMIC found that PubMed lists Dr. Garofalo as an author on over 20 publications between 2005 and 2013, suggesting that while in the Croce laboratory, Dr. Garofalo had the knowledge and experience to understand the rules of scientific publishing and the responsibilities expected of an author on a paper, especially the first author. Thus, the COMIC found that Dr. Garofalo's responses were not credible and did not justify the significant amount of copied text in the eight papers published over six years and examined in this investigation. The COMIC also found that the only evidence repeatedly provided by Dr. Garofalo was her own claim that she was not responsible for the Plagiarism, and this did not meet the burden of proving, by a preponderance of the evidence, any affirmative defense per 42 C.F.R. §93.106(b)(2) or honest error.

#### **Manuscript under Review-Garofalo et al., Cancer Cell 2009 (4 Allegations)**

Garofalo M, Di Leva G, Romano G, Nuovo G, Suh SS, Ngankeu A, Taccioli C, Pichiorri F, Alder H, Secchiero P, Gasparini P, Gonelli A, Costinean S, Acunzo M, Condorelli G, Croce CM. "miR-221&222 regulate TRAIL resistance and enhance tumorigenicity through PTEN and TIMP3 downregulation." *Cancer Cell*. 2009 Dec 8;16(6):498-509.

**Manuscript #1, Allegation #1** - Dr. Garofalo plagiarized ten (10) specific instances of text in *Cancer Cell* 2009.

#### **Finding of Fact:**

- 1) Using a side-by-side comparison, the text alleged to be plagiarized was copied nearly verbatim from ten different sources (see slides 1-14).<sup>98</sup>
- 2) The COMIC highlighted all instances of alleged plagiarism within the publication.<sup>99</sup> The copied text was included in the Introduction and the Discussion sections only.
- 3) Of the ten (10) instances in Garofalo et al., *Cancer Cell* 2009, seven (7) instances represent a single sentence copied. Instances #1 and #3 include three (3) copied sentences, and instance #10 includes two (2) copied sentences.
- 4) Of the ten (10) instances, eight (8) instances cite the original reference for the findings described; however, the source paper from which the text is copied is not cited. For example, the text for instance #3 in Garofalo et al., *Cancer Cell* 2009 includes the citations to the original findings from Leever 1999,

<sup>96</sup> <https://ori.hhs.gov/ori-policy-plagiarism>

<sup>97</sup> In a separate matter (DIO 6962) the COMIC determined that the PI did not write the papers in question and only provided minor edits.

<sup>98</sup> Ex. 661- COMIC Plagiarism Forensics - Garofalo, slides 1-14

<sup>99</sup> Ex. 666 - Marked-Cancer Cell. 2009 Dec 8;16(6)-498-509





Li and Sun 1998, Lee 2005, and Saito 2003; however, a citation to the review paper from which the text is alleged to be plagiarized is not cited (from Planchon, SM, *et al*, J Cell Sci 2008 121, 249-253).

### Respondent's Response:

Dr. Garofalo and Dr. Croce provided the following responses specific for Allegation #1:

- 1) In Dr. Garofalo's written response provided to the CII on November 21, 2017,<sup>100</sup> Dr. Garofalo stated that for instances #1-3 and #10 she had cited the "original source" and that instances #4-8 could be considered common knowledge.<sup>101</sup>
- 2) In the COMIC interview on October 31, 2019, Dr. Garofalo said that the Cancer Cell paper was the first manuscript that she had written alone, and that she had written the questioned sentences.<sup>102</sup> Dr. Garofalo also said that she was the person that submitted the manuscript.<sup>103</sup>
- 3) In the COMIC interview, Dr. Garofalo stated that when she wrote the paper, she thought it was common knowledge and that everyone knew PTEN was a well-known tumor suppressor and she did not think she had to cite such common information.<sup>104</sup>
- 4) In the COMIC interview, Dr. Garofalo said that in 2016 when she was communicating with the editor of Cancer Cell, the editor stated that the Plagiarism allegations were borderline, with less than 5% overlap, so he did not push for correction of the paper.<sup>105</sup>
- 5) Dr. Croce was not asked specifically about this manuscript in his interview with the CII on March 30, 2018. However, Dr. Croce was asked about other Plagiarism allegations and he indicated that the authors from his lab cited the original sources of the findings, but did not always cite the other review papers that had summarized those findings.<sup>106</sup> Dr. Croce defined that as something akin to Plagiarism, or "*a form of Plagiarism*", but without intent.<sup>107</sup>
- 6) In a written response provided to the CII on June 29, 2018,<sup>108</sup> Dr. Croce stated that all of the Plagiarism allegations, including this one, occurred in publications that predated the availability of the iThenticate software at OSU and that it would not have been possible for him to identify any instances of text overlap by reading the papers.
- 7) Additionally, in his written response provided to the CII on June 29, 2018,<sup>109</sup> Dr. Croce stated that he had no knowledge and had no reason to suspect that any of the questioned papers contained text taken from other manuscripts. Dr. Croce stated that prior to July 2014, he had never received any allegations of Plagiarism.
- 8) Dr. Croce's general statements regarding Plagiarism are provided above under [Witness Response](#).

### Respondent's Responsibility and Intent:

Dr. Garofalo claimed that she believed it was proper to cite the original reference for the research to acknowledge who did the work, and not include a citation to the paper or review from which the text was copied. The COMIC finds that the text that Dr. Garofalo copied from the source paper or review article also included the citation(s) to the original work. The COMIC believes that Dr. Garofalo simply copied the text from the source document along with the references. The COMIC finds that this amounts to verbatim copying of text without specific attribution to the source paper and constitutes Plagiarism. Dr. Garofalo also claimed that she had not

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<sup>100</sup> Dr. Garofalo sent a response on 11/20/17, and a follow up on 11/21/17 to indicate she attached the wrong file in her 11/20/17 response ("Response to the allegation" on 11/20; "Response to the allegation MG" on 11/21). This report will use the response dated 11/21/17.

<sup>101</sup> Ex. 150 - Response to the allegations MG. page 3

<sup>102</sup> Ex. 658 - 20191031 - COMIC Interview + Errata - Garofalo, p. 12 lines 8-16 and p. 15, lines 3-4.

<sup>103</sup> Ex. 658 - 20191031 - COMIC Interview + errata - Garofalo, p. 23, lines 1-15

<sup>104</sup> Ex. 658 - 20191031 - COMIC Interview + errata - Garofalo, p. 8, lines 16-25

<sup>105</sup> Ex. 658 - 20191031 - COMIC Interview + errata - Garofalo, p. 10, lines 2-8

<sup>106</sup> Ex. 122a - 20180330-CII Interview + errata - Croce, page 47, lines 12-24, page 48 lines 1-2

<sup>107</sup> Ex. 122a - 20180330-CII Interview + errata - Croce, page 40 lines 10-20

<sup>108</sup> Ex. 152c - Letter - Dr. Wright June 29<sup>th</sup> - Redacted Garofalo, page 1

<sup>109</sup> Ex. 152c - Letter - Dr. Wright June 29<sup>th</sup> - Redacted Garofalo, page 1



been aware of what signifies Plagiarism, or even that Plagiarism is an issue, and that she had not been given proper training or guidance on how to ethically write a manuscript. The COMIC finds that, even without specific training, it strains credibility to believe that any scientist at the graduate school level or above would be unaware of what constitutes Plagiarism, especially one at Dr. Garofalo's level in the Croce laboratory, as a Post-Doctoral Researcher from 2008-2011 and a Research Scientist from 2011-2014. Further, the COMIC identified two (2) papers published earlier when Dr. Garofalo was in the Department of Cellular and Molecular Biology at Federico II University of Naples. One publication in 2005 (Cancer Res. 2005 Aug 1;65(15):6668-75) included Dr. Garofalo as the second co-author and one publication in 2007 Int. J. of Cancer, 2007, 120(6):1215-22) listed Dr. Garofalo as the first author. Thus, by the time Cancer Cell 2009 (Manuscript #1) was published, Dr. Garofalo was already experienced with being an author on scientific publications.

### Significance:

The inclusion of these ten instances of copied text in this manuscript is primarily in background information and does not significantly mislead the reader of the contribution of the author. Based on this, the COMIC believes that if this manuscript were an isolated incident, it may be conceivable that the Plagiarism could be the result of an honest error or inexperience; however, this is one (1) of eight (8) manuscripts published over six (6) years with Dr. Garofalo as the first or senior author, and all the manuscripts include similarly plagiarized text. Manuscript #1 also includes figures that have been falsified (see below). Thus, the COMIC finds that this issue of Plagiarism is more serious when examined in combination with the other similar Plagiarism issues under review, and in totality, represents Research Misconduct.

### Committee Conclusion:

By a preponderance of the evidence, the Committee finds by a vote of 8 in favor to 0 against, that the Respondent intentionally, knowingly, or recklessly copied 10 instances of text and this act constitutes Plagiarism as described in the Policy III. A.

(This publication does not cite PHS support.)

**Manuscript #1, Allegation #2** – Dr. Garofalo falsified Figure 1G and/or 1B in which the same data were used in Cancer Cell 2009, Figure 1G, in lanes 1 and 2 of the beta-actin panel, and in Garofalo et al., PLoS ONE 2008, Figure 1B, in lanes 1 and 2 of the beta-actin panel. The same data (different data than in lanes 1 and 2) were also used in Cancer Cell 2009, Figure 1G, in lane 3 for beta-actin and in Garofalo et al., PLoS ONE 2008, Figure 1B, in lane 2 for the Akt panel.<sup>110</sup>

### Finding of Fact:

- 1) Adobe Photoshop forensic overlay shows that lanes 1 and 2 in the beta-actin panel in Figure 1G are similar to lanes 1 and 2 in the beta-actin panel in Figure 1B in Garofalo et al., PLoS ONE 2008 (see slide #3).<sup>111</sup>
- 2) Adobe Photoshop forensic overlay also demonstrates that lanes 2-3 in the beta-actin panel of Figure 1G are similar to lanes 1-2 in the Akt panel of Figure 1B in Garofalo et al., PLoS ONE 2008 (see slide #3).<sup>112</sup> Thus, the 3-lane panel for beta-actin in Figure 1G was differentially cropped to represent beta-actin and Akt in Figure 1B in PLoS One 2008.
- 3) On February 7, 2020, PLoS One published a "Notification from the PLoS ONE Editors" (<https://journals.plos.org/plosone/article/comment?id=10.1371/annotation/9eb6b941-33a8-4cf0-b112-2f9260145d07>). The notice alerted readers that the bands for b-actin and Akt in Figure 1B in PLoS One 2008, were similar to the b-actin bands in Figures 1G, 3A and 7K in Cancer Cell 2009, and the figures

<sup>110</sup> Allegation #2 from PubPeer was received as described. However, after examination by the COMIC it was determined that the beta-actin panel was differentially cropped using lanes 1-2 as beta-actin in PLoS One 2008 and lanes 2-3 as Akt in PLoS One 2008. This change to the initial allegation is reflected in the Summary of the Investigation Committee Conclusions section.

<sup>111</sup> Ex. 660 - COMIC Figure Forensics-Garofalo\_FINAL, slide 3

<sup>112</sup> Ex. 660 - COMIC Figure Forensics-Garofalo\_FINAL, slide 3



represent different experiments. PLOS One contacted Cancer Cell and also wrote "Based on our assessment and the outcome of our follow-up discussions, the PLOS ONE Editors have determined that these additional issues do not warrant a published editorial notice by PLOS ONE at this time."

**Respondent and Witness Response:**

- 1) In the written response from Dr. Garofalo provided to the CII on November 21, 2017,<sup>113</sup> Dr. Garofalo provided text that she states was previously sent to the Cancer Cell editor. Regarding this allegation, Dr. Garofalo writes, "*Unfortunately, we were not able to find the original blot for the  $\beta$ -actin in Fig.1G and Fig.1B of the [PLoS One] previous paper (Garofalo et al., 2008), therefore we cannot provide any explanation on the possible duplication that may have occurred.*"
- 2) In the interview with the CII on March 2, 2018, Dr. Garofalo stated that she was unable to find the original Western blots used to create Figures 1G and 1B.<sup>114</sup>
  - a. Dr. Garofalo stated that she did not think the bands were the same.<sup>115</sup>
  - b. Dr. Garofalo said that she did not remember if she generated the data for Figure 1G, Cancer Cell 2009 or if she made the published Figure 1G.<sup>116</sup>
  - c. Dr. Garofalo also stated that she did not generate Figure 1B in Garofalo et al., PLoS ONE 2008, and that it could have been generated by someone else in her former laboratory in Italy.<sup>117</sup>
- 3) In her response to the Preliminary CII Report provided on February 15, 2019,<sup>118</sup> Dr. Garofalo wrote that she was performing experiments for the Cancer Cell paper at the same time as she was doing experiments for two other papers (PLoS One, 2008;3(12):e4070 and Oncogene 2008;19;27(27):3845-55) and although she did not write the PLoS One paper or prepare the figures, she did send results to Dr. Gerolama Condorelli in Italy. Dr. Garofalo wrote that it was "*possible that films for the two manuscripts were acquired together, mislabeled and mixed-up or I sent slides/data for the two studies simultaneously and this could have generated the confusion about the figures.*" Dr. Garofalo also wrote that the mistake does not change the conclusions represented in the papers as there are other experiments in the papers confirming the conclusions as well as other publications from different groups that confirmed the results and findings.
- 4) In the COMIC interview on October 31, 2019, Dr. Garofalo said that at the time the Cancer Cell 2009 paper was prepared she was writing the manuscript, performing the experiments and asked other people to help with the construction of the figures. Dr. Garofalo said that since she had so many other things to do, any mistake was unintentional.<sup>119</sup>
- 5) During the Inquiry, Dr. Croce did not respond specifically to this allegation, but he is listed as a co-corresponding author with Gerolama Condorelli (University of Naples), who was Dr. Garofalo's Ph.D. advisor.

**Respondent's Responsibility and Intent:**

The COMIC believes that as the first author listed on the Cancer Cell 2009 and the PLoS One 2008 publications, Dr. Garofalo was responsible for the validity of the published data and for the reuse of the same data for results representing two different proteins (beta-actin and Akt). The COMIC is not persuaded by Dr. Garofalo's explanation that mistakes were made because she was too busy, since for the five (5) allegations under review involving figures, Dr. Garofalo claims that the problems resulted from honest error, including in Cancer Cell 2009 (Allegations #2, #3, #4), Nature Medicine 2012 (Allegation #13), and Oncogene 2008/ PNAS 2008 (Allegation #16). For this Allegation #2, the COMIC believes that it is possible that a mistake can occur with the reuse of control data, which often have similar intensities across all samples; however, in this case the

<sup>113</sup> Ex. 150 - Response to the allegations MG, page 1

<sup>114</sup> Ex. 119 - 20180302-CII Interview + errata –Garofalo, page 24, lines 13-16

<sup>115</sup> Ex. 119 - 20180302-CII Interview + errata –Garofalo, page 24, line 12 and page 25, line 21

<sup>116</sup> Ex. 119 - 20180302-CII Interview + errata –Garofalo page 26, lines 17-24

<sup>117</sup> Ex. 119 - 20180302-CII Interview + errata –Garofalo page 28, lines 9-10 and line 23 and page 30, lines 12-14

<sup>118</sup> Ex. 384 - Response to the CII report MG

<sup>119</sup> Ex. 658 - 20191031 - COMIC Interview + errata - Garofalo, p. 27-28



same three (3) lanes for the beta-actin panel, Figure 1G in Cancer Cell 2009 were differentially cropped – using lanes 1-2 to represent beta-actin in Figure 1B in PLoS One 2008, and using lanes 2-3 to represent Akt, a completely different protein, in Figure 1B in PLoS One 2008. The COMIC believes that the use of data in this way was deliberate and is unlikely to be the result of honest error.

As described above, initially Dr. Garofalo claimed that she could not find any data for either publication, and that she did not remember if she generated the data or made the published figure for Figure 1G, in Cancer Cell 2009. Later in the response to the Preliminary CII Report, Dr. Garofalo said that she was doing the experiments simultaneously for both Cancer Cell 2009 and PLoS One 2008, and then sending data to Italy for PLoS One 2008. In the COMIC interview, Dr. Garofalo claimed that at the time the Cancer Cell 2009 paper was prepared she was writing the manuscript, performing the experiments, and asked other people to help with the construction of the figures. Thus, the COMIC believes that Dr. Garofalo was very involved in the research for both the Cancer Cell 2009 and PLoS One 2008 publications, and this is supported by Dr. Garofalo being the first author on both publications.

The COMIC believes it is disingenuous for Dr. Garofalo, who is the first author, to claim that an unnamed person(s) in the Croce lab or in the lab in Italy, could have been responsible for making the figures in question without providing any evidence to prove the credibility of her statements. The COMIC believes that based on Dr. Garofalo's involvement in this research, even if Dr. Garofalo did send the data to Italy for the figures in PLoS One 2008, it was Dr. Garofalo's responsibility to ensure that the data were labeled properly so that mistakes would not be made. The COMIC also notes that raw data films provided to the CII by Dr. Garofalo for Allegations #3 and #4 (see below), include hand-written labels on the films and weaken Dr. Garofalo's explanation that an error was made by someone else because things were mislabeled or mixed up. The COMIC finds that this allegation is not an isolated incident. In combination with other issues of falsification in this manuscript and other manuscripts, which show similar reuse of data to represent results of different experiments, the COMIC finds that this issue of falsification of data is serious and, in totality, represents Research Misconduct.

#### **Committee Conclusion:**

By a preponderance of the evidence, the Committee finds by a vote of 8 in favor to 0 against, that the Respondent intentionally, knowingly, or recklessly falsified data and this act constitutes Falsification as described in the Policy III. A.

(This publication does not cite PHS support.)

**Manuscript #1, Allegation #3** - Dr. Garofalo falsified Figure 5B and/or 5E, in which the same data were used as the Akt tot panel and as the beta-actin panel in Figure 5B, and also used in Figure 5E as the beta-actin panel (flipped vertically).

#### **Finding of Fact:**

- 1) Adobe Photoshop forensic overlay shows that the beta-actin panel in Figure 5B is similar to the Akt tot panel (when Akt is stretched vertically). The beta-actin panel in Figure 5B (when rotated 180 degrees) is also similar the beta-actin blot in Figure 5E (see slides 4-5).<sup>120</sup> Thus, a single 3-lane panel with various manipulations was used to represent beta-actin in Figures 5B and 5E, and also used to represent Akt tot in Figure 5B.
- 2) Dr. Garofalo did not dispute the allegation but stated she believed it was an honest error that arose during the revision of the paper and figures.

#### **Respondent's Response**

- 1) In the written response that Dr. Garofalo provided to the CII on November 21, 2017,<sup>121</sup> Dr. Garofalo

<sup>120</sup> Ex. 660 - COMIC Figure Forensics-Garofalo\_FINAL, slides 4-5

<sup>121</sup> Ex. 150 - Response to the allegations MG, page 1



included a copy of the correspondence she had with the Cancer Cell editor regarding Figure 5, and Dr. Garofalo wrote, "*We realized that during the assembling of Figure 5 there has been a duplication of the  $\beta$ -actin and total AKT western blots in panel 5B and of the  $\beta$ -actin in panel 5E. Therefore, I am attaching the correct blots for total AKT and corresponding  $\beta$ -actin for Fig. 5B. We are also providing the original blots for the panel in Fig. 5E and the corresponding  $\beta$ -actin. We believe that this mistake occurred during the revision of the paper when the figure has been split in multiple panels.*"

- 2) In the response on November 21, 2017,<sup>122</sup> Dr. Garofalo also included three documents that purportedly represented the scans of the original data that she had sent to Cancer Cell (for b-actin Fig.5B,<sup>123</sup> tot AKT Fig.5B,<sup>124</sup> and b-actin Fig.5E<sup>125</sup> (see also slide #6<sup>126</sup>).
- 3) The COMIC notes that the film for total AKT ("tot AKT Fig.5B") does *not* show equal levels of protein expression as reported in the published image.
- 4) The COMIC also notes that the presentation of these three films, with no supporting notebook documentation or written dates on the films, makes it impossible to verify whether these data were generated when the Cancer Cell 2009 paper was written.
- 5) In her interview with the CII on March 2, 2018, Dr. Garofalo stated that the panels were mixed-up during figure preparation and there was no intention to falsify data.<sup>127</sup>
- 6) In the COMIC interview on October 31, 2019, Dr. Garofalo claimed that she generated Figure 5 but had asked other people in the lab for help with scanning the films or making a PowerPoint presentation and then she would generate the figure.<sup>128</sup> Dr. Garofalo claimed that any duplication or flipping was a mistake and unintentional.<sup>129</sup>

#### **Respondent's Responsibility and Intent:**

The COMIC believes that as the first author listed on the Cancer Cell 2009 publication, Dr. Garofalo was responsible for the validity of the published data and for the reuse of the same data to represent the results of two different proteins (beta-actin, in 2 different panels, and Akt tot in one panel). The COMIC is not persuaded by Dr. Garofalo's explanation that this was a mistake that resulted from an honest error, since Dr. Garofalo makes the same claim for each of the five (5) allegations involving figures that are under review, including Cancer Cell 2009 (Allegations #2, #3, #4), Nature Medicine 2012 (Allegation #13), and Oncogene 2008 and PNAS 2008 (Allegation #16).

For Allegation #3, the COMIC notes that the film presented by Dr. Garofalo for total Akt shows unequal levels of protein, and, although it is unknown if this is a contemporaneous film, the unequal levels may be a possible motive for the duplication in order to show equal loading. The COMIC also notes that although the reuse of a complete 3-lane panel with the same intensities could conceivably result from an honest error; the reuse of the panel in this case includes vertical stretching and flipping, which undermines the honest error argument. The COMIC specifically asked Dr. Garofalo, ". . . *it would be helpful for you to explain to us how unintentionally some western blot gets rotated, copied, and put in two places and so, please, because it's really important for the committee to be able to understand how something like that happens unintentionally.*"<sup>130</sup> Dr. Garofalo responded that the films were not labeled prior to scanning and she had asked "other people" to scan films. Dr. Garofalo said that sometimes the films were scanned in the wrong directions and that is what created

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<sup>122</sup> Ex. 150 - Response to the allegations MG

<sup>123</sup> Ex. 154 - b-actin Fig.5B

<sup>124</sup> Ex. 155 - tot AKT Fig.5B

<sup>125</sup> Ex. 153 - b-actin Fig.5E

<sup>126</sup> Ex. 660 - COMIC Figure Forensics-Garofalo\_FINAL, slide 6

<sup>127</sup> Ex. 119 - 20180302-CII Interview + errata - Garofalo, page 37, lines 5-7

<sup>128</sup> Ex. 658 - 20191031 - COMIC Interview + errata - Garofalo, pp. 35-36, p. 42

<sup>129</sup> Ex. 658 - 20191031 - COMIC Interview + errata - Garofalo, pp. 29, 37-38

<sup>130</sup> Ex. 658 - 20191031 - COMIC Interview + errata - Garofalo, 41, lines 1-10





the problems.<sup>131</sup> The COMIC believes that the carelessness with which Dr. Garofalo prepared this figure is not the standard that a typical researcher would use to create a figure for publication. The COMIC also believes it is disingenuous for Dr. Garofalo, who is the first author, to claim that some unnamed person(s) in the Croce lab could have been responsible for providing problematic scans, without any evidence to prove the credibility of this statement. Since Dr. Garofalo admitted to making the figure in question, the COMIC believes she was responsible for ensuring that the data she used were valid, properly labeled, and accurately incorporated into the figure. Dr. Garofalo's explanation about mistakes happening during scanning does not account for the vertical stretching of the Akt tot panel in Figure 5B.

#### **Significance:**

The COMIC finds that the inclusion of the total Akt control panel with evenly loaded levels of protein is inconsistent with the primary data provided by Dr. Garofalo for total Akt, which shows unequal levels of protein. The COMIC finds that the use of the evenly loaded control total Akt data misrepresents the phospho-Akt data and the downstream interpretations and effects of the treatments.

The COMIC believes that the preponderance of the evidence does not support that this allegation resulted from honest error. The combination of reusing the panel with stretching and flipping and of having other similar allegations of data reuse in other figures in this paper increases the severity of the falsification. The COMIC believes this issue of falsification of data is serious and, in totality, represents Research Misconduct.

#### **Committee Conclusion:**

By a preponderance of the evidence, the Committee finds by a vote of 8 in favor to 0 against, that the Respondent intentionally, knowingly, or recklessly falsified Figure 5B and/or 5E in Cancer Cell 2009 and this act constitutes Falsification as described in the Policy III. A. (This publication does not cite PHS support.)

**Manuscript #1, Allegation #4** - Dr. Garofalo falsified Figure 7D and/or 7F, in which the same data were used in lane 1 of the MET blot (Calu-1) in Figure 7D and used in lane 3 of the MET blot (GTL16) in Figure 7F.<sup>132</sup>

#### **Finding of Fact:**

- 1) Adobe Photoshop forensic overlay shows that lane 1 of the MET blot in Figure 7D is from the same source as lane 3 of the MET blot in Figure 7F (see slide 8<sup>133</sup>). Additionally, there is a unique background artifact (small dot) seen above the right side of the MET band in both Figures 7D and 7F (see green arrows on slide 8<sup>134</sup>).
- 2) In the written response to the CII on November 21, 2017,<sup>135</sup> Dr. Garofalo provided a scan of a film labeled "Fig.7E-F," which she claimed represented the original experiment for Figure 7.<sup>136</sup>
- 3) Forensic analysis of the "Fig.7E-F" film<sup>137</sup> compared to the published figure shows that "Fig.7E-F" (lanes 3-5), which Dr. Garofalo labeled as representing MET (in GTL16 cells), were used in the published Figure 7F for MET (GTL16 cells) (see overlay 1. on slide 10).
- 4) Forensic analysis also shows that "Fig.7E-F" (lanes 5-6), purportedly representing MET (GTL16/Su11274

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<sup>131</sup> Ex. 658 - 20191031 - COMIC Interview + errata - Garofalo, p. 41-42

<sup>132</sup> Allegation #4 from PubPeer was received as described. However, after the allegation was reviewed by the COMIC, it was determined that MET lanes 3-6 on the film provided by Dr. Garofalo were differentially cropped using lanes 3-5 as MET GTL16 in Figure 7F and lanes 5-6 as MET Calu-1 in Figure 7D. This change to the initial allegation is reflected in the Summary of the Investigation Committee Conclusions section.

<sup>133</sup> Ex. 660 - COMIC Figure Forensics-Garofalo\_FINAL, slide 8

<sup>134</sup> Ex. 660 - COMIC Figure Forensics-Garofalo\_FINAL, slide 8

<sup>135</sup> Ex. 150 - Response to the allegations MG, page 1

<sup>136</sup> Ex. 192 - Fig.7E-F

<sup>137</sup> Ex. 660 - COMIC Figure Forensics-Garofalo\_FINAL, slides 9-10



treated) and an unlabeled lane, were used in published Figure 7D for MET (Calu-1 cells) (see overlay 2. on slide 10).

- 5) Forensic analysis shows that the lanes on the film "Fig.7E-F" labeled to represent MET (Calu-1 cells) (lanes 1-2) do not overlay with published Figure 7D for MET (Calu-1) (see overlay 3. on slide 10).
- 6) Handwritten labels at the bottom of the "Fig.7E-F" film appear to have been cropped off and the text labels were provided to the CII by Dr. Garofalo (see slide #9).<sup>138</sup> In addition, the eight lanes on the scanned film do not align with the 7 labels added by Dr. Garofalo. These facts lead the COMIC to question the authenticity of the "Fig.7E-F" film, and thus the COMIC believes that the published Figures 7D and 7F are not valid.
- 7) Based on the above forensic analysis, even if one assumes the "Fig.7E-F" film was properly labeled by Dr. Garofalo, which does not appear to be the case, arbitrary lanes were chosen from the film and used for the published Figures 7D and 7F.
  - a. Specifically, "Fig.7E-F" film lanes 3-5 for MET (GTL16) were used in Figure 7F for MET (GTL16) but then "Fig.7E-F" lanes 5-6, labeled for MET (GTL16) were also used in Figure 7D to represent MET (Calu-1). In addition, "Fig.7E-F" lanes 1-2 that were labeled for MET (Calu-1), had not been used in Figure 7D for the MET (Calu-1) experiment.

### **Respondent and Witness Response**

- 1) In the written response Dr. Garofalo provided to the CII on November 21, 2017,<sup>139</sup> Dr. Garofalo indicated that if a duplication occurred it was unintentional as there were several replicates of the experiment that could have been chosen for the figure.
- 2) In her interview with the CII on March 2, 2018, Dr. Garofalo stated that she did not remember if she generated the data for Figure 7D.<sup>140</sup>

### **Respondent's Responsibility and Intent:**

The COMIC believes that as the first author listed on the Cancer Cell 2009 publication, Dr. Garofalo was responsible for the validity of the published data and for the reuse of the same raw data to represent the results for the MET protein from different cell types. The COMIC is not persuaded by Dr. Garofalo's explanation that she made this mistake because she was too busy, since Dr. Garofalo makes the same claim for an honest error to explain the problems involving figures under review for each of the five (5) allegations, including Cancer Cell 2009 (Allegations #2, #3, #4), Nature Medicine 2012 (Allegation #13), and Oncogene 2008 and PNAS 2008 (Allegation #16).

For Allegation #4, overall, the COMIC does not believe that the raw data provided by Dr. Garofalo as "Fig.7E-F" is an accurate representation of the data in Figure 7 and believes that both Figure 7D and 7F were falsified. The falsification is similar to other allegations under review with differential cropping of raw data, in this case to represent proteins from completely different cell types, Calu-1 or GTL16. The COMIC believes that the use of raw data in this way was deliberate and is unlikely to be the result of honest error, as claimed. Since the questioned data represents experimental results, not control data, the seriousness and significance of this reuse of data is increased.

The COMIC believes that, like the other allegations of figure falsification, Dr. Garofalo was involved in the research for the Cancer Cell 2009 publication, and this is supported by Dr. Garofalo being the first author on the publication. The COMIC believes that even if this allegation were an isolated incident, it is not conceivable that this falsification, by differentially cropping raw data from a labeled film, would be the result of honest error. In combination with additional issues of falsification in this manuscript, having similar reuse of data to represent different experimental results, the COMIC finds that this issue of falsification of data is serious and represents

<sup>138</sup> Ex. 660 - COMIC Figure Forensics-Garofalo\_FINAL, slide 9

<sup>139</sup> Ex. 150 - Response to the allegations MG, page 2

<sup>140</sup> Ex. 119 - 20180302-CII Interview + errata -Garofalo, page 42, line 1



Research Misconduct.

**Committee Conclusion:**

By a preponderance of the evidence, the Committee finds by a vote of 8 in favor to 0 against, that the Respondent intentionally, knowingly, or recklessly falsified Figure 7 in Cancer Cell 2009 and this act constitutes Falsification as described in the Policy III. A.

(This publication does not cite PHS support.)

**Manuscript under Review- Garofalo et al., Curr Mol Med 2012 (1 Allegation)**

Garofalo M, Quintavalle C, Romano G, Croce CM, Condorelli G."miR221/222 in cancer: their role in tumor progression and response to therapy." Curr Mol Med. 2012 Jan; 12 (1): 27-33.

**Manuscript #2, Allegation #5** - Dr. Garofalo plagiarized fourteen (14) specific instances of text in Curr Mol Med 2012.

**Finding of Fact:**

- 1) Using a side-by-side comparison, the text that was alleged to be plagiarized was copied nearly verbatim from fourteen (14) different sources (see slides 15-33).<sup>141</sup>
- 2) In Dr. Garofalo's written response provided to the CII on November 21, 2017,<sup>142</sup> Dr. Garofalo wrote that instances #2, #6, #9 and #13 were from manuscripts previously published from Dr. Croce's laboratory. Dr. Garofalo also wrote that for instances #7, #8, #10 and #14 the original citations have been provided and that for instances #1, #3, #5, #11 the text could be considered common knowledge.
- 3) The COMIC highlighted all of the instances of alleged Plagiarism within the publication (and specifically excluded any instances of "self-plagiarism").<sup>143</sup>
- 4) The COMIC finds six (6) of the fourteen (14) instances (#2, #6, #7, #9, #10, #13) represent failure to cite their own publications (i.e., "self-plagiarism"), as Dr. Croce and/or Dr. Garofalo are listed as author(s) on the sources. The COMIC finds these six (6) instances do not meet the definition of Plagiarism. While the COMIC recognizes that these specific instances do not meet the definition of Research Misconduct, these instances still represent verbatim copying of text without specific attribution to source papers, which is improper.
- 5) The COMIC finds that for Allegation #5, eight (8) of the fourteen (14) alleged instances appear to represent issues of Plagiarism.
- 6) The COMIC notes that Curr Mol Med. 2012 is a review article and the copied text appears in different sections of the review.

**Respondents Response:**

Dr. Garofalo's statements regarding Plagiarism are provided above under [Respondent Responses Regarding Plagiarism](#).

Dr. Croce's statements regarding Plagiarism are provided above under [Witness Response](#).

**Respondent's Responsibility and Intent:**

The specific comments regarding Dr. Garofalo's responsibility and intent regarding Plagiarism are provided above under [Respondent's Responsibility and Intent](#) for M#1, A#1. In brief, the COMIC concludes that eight (8) of the fourteen (14) alleged instances in Allegation #5 appear to represent issues of Plagiarism and that this is one (1) of eight (8) manuscripts published over six (6) years with Dr. Garofalo as the first, or senior, author that all include similarly plagiarized text. The COMIC finds that this issue of Plagiarism is more serious in combination with all the other similar Plagiarism issues, and in totality, represents Research Misconduct.

<sup>141</sup> Ex. 661 - COMIC Plagiarism Forensics - Garofalo, slides 15-33

<sup>142</sup> Ex. 150 - Response to the allegations MG, page 4

<sup>143</sup> Ex. 663 - Marked- Curr Mol Med. 2012 12- 2733



### Committee Conclusion:

By a preponderance of the evidence, the Committee finds by a vote of 8 in favor to 0 against that the Respondent intentionally, knowingly, or recklessly copied eight (8) instances of text and this act constitutes Plagiarism as described in the Policy III. A.

(This publication does not cite PHS support.)

### Manuscript under Review- Garofalo et al., PLoS One 2013 (1 Allegation)

Garofalo M, Jeon YJ, Nuovo GJ, Middleton J, Secchiero P, Joshi P, Alder H, Nazaryan N, Di Leva G, Romano G, Crawford M, Nana-Sinkam P, Croce CM. "MiR-34a/c-Dependent PDGFR- $\alpha/\beta$  Downregulation Inhibits Tumorigenesis and Enhances TRAIL-Induced Apoptosis in Lung Cancer." PLoS One. 2013 Jun 21; 8 (6): e67581.

**Manuscript #3, Allegation #6** - Dr. Garofalo plagiarized eleven (11) specific instances of text in PLoS One 2013.

### Finding of Fact:

- 1) Using a side-by-side comparison, the text that was alleged to be plagiarized was copied nearly verbatim from eleven (11) different sources (see slides 34-49).<sup>144</sup>
- 2) The COMIC highlighted all instances of alleged plagiarism within the publication (if included, the COMIC omitted any instances of "self-plagiarism").<sup>145</sup>
- 3) The COMIC notes that PLoS One 2013 is a research article and the copied text is in the Abstract, in the Introduction, and in the Discussion sections. The entire Introduction section is copied from other sources, with the exception of the last 2 sentences in the Introduction.
- 4) The COMIC finds that most of the copied text is background information and does not affect the research results. Of the eleven (11) specific instances of copied text, instances #1, #2, #4, and #9 include 1 sentence of copied text; instances #6 and #7 are 2 sentences; instances #3 and #11 are 3 sentences; instance #10 is 4 sentences; instance #8 is 5 sentences; and instance #9 is 6 sentences.
- 5) Of the eleven (11) specific instances of copied text, in most cases where references to the original research findings are present in PLoS One 2013, the specific reference is also included in the text copied from the source paper.

### Respondents Response:

- 1) For Allegation #6, in her written response provided to the CII on November 21, 2017,<sup>146</sup> Dr. Garofalo wrote that this manuscript was corrected on June 25, 2015, in order to acknowledge the authors that were not cited in the text.
- 2) The correction reads: "*After the publication of the article, 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.*"<sup>147</sup>
- 3) Dr. Garofalo's general statements regarding Plagiarism are provided above under [Respondent Responses Regarding Plagiarism](#).
- 4) Dr. Croce's statements regarding Plagiarism are provided above under [Witness Response](#).

<sup>144</sup> Ex. 661 - COMIC Plagiarism Forensics - Garofalo, slides 34-49

<sup>145</sup> Ex. 669 - Marked-PLOS 2013 Garofalo et al.

<sup>146</sup> Ex. 150 - Response to the allegations MG, page 4

<sup>147</sup> Ex. 020 - Correction-PLOS 2013 Garofalo et al.



### **Respondent's Responsibility and Intent:**

The specific comments regarding Dr. Garofalo's responsibility and intent regarding Plagiarism are provided above under [Respondent's Responsibility and Intent](#) for M#1, A#1. The COMIC finds that a citation to the original findings does not justify the verbatim copying of text without specific attribution to the paper summarizing that finding. The COMIC finds that although the Plagiarism does not alter the research results, there is significant copying of background text from other sources in this paper. The COMIC finds that for Allegation #6, the correction appropriately addresses six (6) of the eleven (11) instances of plagiarism (instances #2, #5, #7, #8, #10, #11) but does not address instances #1, #3, #4, #6, and #9. The COMIC concludes that this is one (1) of eight (8) manuscripts published over six (6) years with Dr. Garofalo as the first, or senior, author that all include similarly plagiarized text. Thus, the COMIC finds that this issue of Plagiarism is more serious in combination with all the other similar Plagiarism issues, and in totality, represents Research Misconduct.

### **Committee Conclusion:**

By a preponderance of the evidence, the Committee finds by a vote of 8 in favor to 0 against that the Respondent intentionally, knowingly, or recklessly copied eleven (11) specific instances of text and this act constitutes Plagiarism as described in the Policy III. A and 42 C.F.R. § 93.103 (b). (This publication does cite PHS support.)

### **Manuscript under Review – Garofalo and Croce Drug Resist Update 2013 (1 Allegation)**

Garofalo M, Croce CM. "MicroRNAs as therapeutic targets in chemoresistance." *Drug Resist Updates*, 2013 Jul-Nov; 16 (3-5): 47-59. Epub 2013 Jun 10.

**Manuscript #4, Allegation #7** - Dr. Garofalo plagiarized nine (9) specific instances of text in *Drug Resist Updates* 2013.

### **Finding of Fact:**

- 1) Using a side-by-side comparison, the text that was alleged to be plagiarized was copied nearly verbatim from nine (9) different sources (see slides 50-61).<sup>148</sup>
- 2) The COMIC highlighted all instances of alleged plagiarism within the publication (if included, the COMIC omitted any instances of "self-plagiarism").<sup>149</sup>
- 3) In her written response provided to the CII on November 21, 2017,<sup>150</sup> Dr. Garofalo wrote that instances #1, #2 and #4 occur in the Abstract of the manuscript where citations are generally not reported; instances #3 and #5 are common knowledge; instances #7 and #8 have citations to the original source; and instances #6 and #9 do not have any citations.
- 4) *Drug Resist Updates* 2013 is a review article. The plagiarized text appears in the Abstract and in 3 other sections of the article.
- 5) The COMIC finds that 8 of 9 instances (instances #1- #6, #8, #9) include one sentence or phrase of copied text and instance #7 includes 3 sentences.
- 6) Of the nine (9) specific instances of copied text, two instances #7 and #8 had references to the original research findings and the specific reference was also included in the text copied from the source paper.

### **Respondents Response:**

Dr. Garofalo's statements regarding Plagiarism are provided above under [Respondent Responses Regarding Plagiarism](#).

Dr. Croce's statements regarding Plagiarism are provided above under [Witness Response](#).

### **Respondent's Responsibility and Intent:**

<sup>148</sup> Ex. 661 - COMIC Plagiarism Forensics - Garofalo, slides 50-61

<sup>149</sup> Ex. 667 - Marked-Garofalo M Croce CM Drug Resistance Updates 2013

<sup>150</sup> Ex. 150 - Response to the allegations MG





The specific comments regarding Dr. Garofalo's responsibility and intent regarding Plagiarism are provided above under [Respondent's Responsibility and Intent](#) for M#1, A#1. The COMIC finds that a reference to the original findings that are also included in the source paper, does not justify the verbatim copying of text. The COMIC concludes that although this is a review article and the copied text are generally background information, this is one (1) of eight (8) manuscripts published over six (6) years with Dr. Garofalo as the first, or senior, author that all include similarly plagiarized text. The COMIC finds that this issue of Plagiarism is more serious in combination with all the other similar Plagiarism issues, and in totality, represents Research Misconduct.

**Committee Conclusion:**

By a preponderance of the evidence, the Committee finds by a vote of 8 in favor to 0 against that the Respondent intentionally, knowingly, or recklessly copied nine (9) specific instances of text and this act constitutes Plagiarism as described in the Policy III. A.

(This publication does not cite PHS support).

**Manuscript under Review – Garofalo and Croce, Annu Rev Pharm & Tox 2011 (1 Allegation)**

Garofalo, M and Croce CM. "microRNAs: Master Regulators as Potential Therapeutics in Cancer." Annual Review of Pharmacology and Toxicology 2011 51:1, 25-43.

**Manuscript #5, Allegation #8** - Dr. Garofalo plagiarized three (3) specific instances of text in Annu Rev Pharm & Tox 2011.

**Finding of Fact:**

- 1) Using a side-by-side comparison, the text alleged to be plagiarized was copied nearly verbatim from three (3) different sources (see slides 62-67).<sup>151, 152</sup>
- 2) The COMIC highlighted all instances of alleged plagiarism within the publication (if included, the COMIC omitted any instances of "self-plagiarism").<sup>153</sup>
- 3) In her written response provided to the CII on November, 21 2017,<sup>154</sup> Dr. Garofalo indicated that she did not "*steal any intellectual properties since the reported sentences refer to previously published scientific findings.*"
- 4) In her written response on November, 21 2017,<sup>155</sup> Dr. Garofalo stated that instance #1 was from a figure legend where citations are not reported, that in instance #2 the reference was missing, and instance #3 could be considered common knowledge.
- 5) The COMIC finds that instance #1 is two (2) copied sentences in a figure legend, and instances #2 and #3 are 2 copied sentences.
- 6) In her written response on November, 21 2017,<sup>156</sup> Dr. Garofalo stated that the copied text was only 1.4% of the total words in the Annual Rev Pharm & Tox 2011 review article.

**Respondents Response:**

Dr. Garofalo's statements regarding Plagiarism are provided above under [Respondent Responses Regarding Plagiarism](#).

Dr. Croce's statements regarding Plagiarism are provided above under [Witness Response](#).

**Respondent's Responsibility and Intent:**

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<sup>151</sup> Ex. 661 - COMIC Plagiarism Forensics - Garofalo, slides 62-67

<sup>152</sup> Ex. 210 - Annu Rev Pharm Tox 2011 forensics - plagiarism

<sup>153</sup> Ex. 664 - Marked- Garofalo Annu Rev Pharma Toxicol 2011

<sup>154</sup> Ex. 150 - Response to the allegations MG, page 2

<sup>155</sup> Ex. 150 - Response to the allegations MG, page 5-6

<sup>156</sup> Ex. 150 - Response to the allegations MG, page 5



The specific comments regarding Dr. Garofalo's responsibility and intent regarding Plagiarism are provided above under [Respondent's Responsibility and Intent](#) for M#1, A#1. The COMIC concludes that although this is a review article and there are only three (3) instances of copied text that are generally background information, this review article is one (1) of eight (8) manuscripts published over six (6) years with Dr. Garofalo as the first, or senior, author that all include similarly plagiarized text. The COMIC finds that this issue of Plagiarism is more serious in combination with all the other similar Plagiarism issues, and in totality, represents Research Misconduct.

#### **Committee Conclusion:**

By a preponderance of the evidence, the Committee finds by a vote of 8 in favor to 0 against that the Respondent intentionally, knowingly, or recklessly copied three (3) specific instances of text and this act constitutes Plagiarism as described in the Policy III. A.

(This publication does not cite any funding support).

#### **Manuscript under Review- Garofalo et al., Oncogene 2008 (2 Allegations)**

**[NOTE: The COMIC's determination based on the analysis below for Allegation #12 was changed as a result of the Respondent's response to the Preliminary Report of the Investigation.]**

Garofalo M, Quintavalle C, Di Leva G, Zanca C, Romano G, Taccioli C, Liu CG, Croce CM, Condorelli G. "MicroRNA signatures of TRAIL resistance in human non-small cell lung cancer." *Oncogene*. 2008 Jun 19; 27 (27): 3845-55. Epub 2008 Feb 4 **Correction: 01/04/2021**<sup>157, 158</sup>

**Manuscript #6, Allegation #12** – Dr. Garofalo plagiarized one (1) specific instance of text in *Oncogene* 2008.

#### **Finding of Fact:**

- 1) Using a side-by-side comparison, the text that was alleged to be plagiarized was copied nearly verbatim from one (1) different source (see slide 68).<sup>159</sup>
- 2) The COMIC highlighted the instances of alleged Plagiarism within the publication.<sup>160</sup>
- 3) The questioned text includes three (3) copied sentences in the introduction section of Manuscript #6. The text is copied verbatim from Voortman, *Mol Cancer Ther* 2007. A reference to the original research finding is in Manuscript #6 and is also present in the source paper, Voortman, *Mol Cancer Ther* 2007.
- 4) In the written response to the allegations, provided on April 2, 2019,<sup>161</sup> Dr. Garofalo stated that she did not write the manuscript and instead claimed it was written by the corresponding author, Dr. Condorelli.
- 5) In his written response, provided on April 11, 2019,<sup>162</sup> Dr. Croce indicated that he did not write the allegedly plagiarized text.
- 6) In his April 11, 2019, written response, Dr. Croce further indicated that the allegedly plagiarized text was part of the Introduction and was summarizing "well-known background knowledge."<sup>163</sup>
- 7) In his April 11, 2019, written response, Dr. Croce included the Office of Research Integrity's policy on plagiarism and suggested that this allegation would not be considered plagiarism by those standards.<sup>164</sup>
- 8) The correction published on January 4, 2021, did not address the instances of plagiarism identified in this manuscript.

<sup>157</sup> Ex. 761 – Correction-Garofalo et al *Oncogene* 2008

<sup>158</sup> The correction pertains only to Figures 4C and 7A.

<sup>159</sup> Ex. 661- COMIC Plagiarism Forensics - Garofalo, slide 68

<sup>160</sup> Ex. 668 - Marked-Garofalo *Oncogene* 2008

<sup>161</sup> Ex. 489 - 20190402-Garofalo Response to Allegations

<sup>162</sup> Ex. 500b - Croce Response to All\_page 4-8 : see page 4

<sup>163</sup> Ex. 500b - Croce Response to All\_page 4-8: see page 6

<sup>164</sup> Ex. 500b - Croce Response to All\_page 4-8 : see page 7



### Respondents Response:

Dr. Garofalo's statements regarding Plagiarism are provided above under [Respondent Responses Regarding Plagiarism](#).

Dr. Croce's statements regarding Plagiarism are provided above under [Witness Response](#).

### Respondent's Responsibility and Intent:

The specific comments regarding Dr. Garofalo's responsibility and intent regarding Plagiarism are provided above under [Respondent's Responsibility and Intent](#) for M#1, A#1. Although Dr. Garofalo claimed that the manuscript was written by Dr. Condorelli, the COMIC notes that M#1, #2, and #7 also include Dr. Condorelli as an author and were written in 2009 and 2012. Given that Dr. Garofalo does not claim that Dr. Condorelli was involved in writing of these papers, and the issues of Plagiarism are the same for the eight (8) manuscripts in question, the COMIC believes that it is more likely than not that Dr. Garofalo was responsible for the plagiarized text. The COMIC concludes that although there are only three (3) sentences of copied text that appear to be background information, this article is one (1) of eight (8) manuscripts published over six (6) years with Dr. Garofalo as the first, or senior, author that all include similarly plagiarized text. Of additional concern is that despite knowledge of plagiarism in this manuscript, a correction to Figures 4C and 7A was published on January 4, 2021, without a correction of the plagiarized text. Thus, the COMIC finds that the issue of Plagiarism is more serious in combination with all the other similar Plagiarism issues, and in totality, represents Research Misconduct. The COMIC determined that the editor should be informed of the additional issues with this manuscript not addressed by the correction.

### Committee Conclusion:

By a preponderance of the evidence, the Committee finds by a vote of 8 in favor to 0 against that the Respondent intentionally, knowingly, or recklessly copied one (1) specific instance of text and this act constitutes Plagiarism as described in the Policy III. A.

(This publication does not cite any PHS support).

**Manuscript #6, Allegation #16**<sup>165</sup> – Dr. Garofalo falsified Northern blot data in Oncogene 2008 and/or PNAS 2008, by the reuse of the same data for the U6 blot in Figure 3B in Oncogene 2008 and the U6 blot in Figure 4C of PNAS 2008, Mar 11;105(10):3945-50,<sup>166</sup> which represent different experimental conditions and treatments.

### Finding of Fact:

- 1) Adobe Photoshop forensic overlay shows that the four (4) lane U6 blot of Figure 3b in Garofalo Oncogene 2008 is identical to the four (4) lane U6 blot of Figure 4C in Garzon PNAS 2008 (see slides #12-14).<sup>167</sup> This is not scientifically valid as these figures represent different experimental conditions.
- 2) Dr. Garofalo is a co-first author, with Dr. Ramiro Garzon, on the PNAS 2008 paper. Dr. Garzon is not an author on the Garofalo Oncogene 2008 paper.
- 3) On September 12, 2019, the co-first author Dr. Garofalo provided an email<sup>168</sup> with 3 attachments.
  - a. The attachment "GarafaloetalFig3.ppt"<sup>169</sup> is purported to be the source data for Figure 3B in Garofalo Oncogene 2008.

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<sup>165</sup> The original notification of this allegation referenced Manuscript #10, Allegation #16 (see Ex. 631 - 20190828 - Notification of Allegations\_Garofalo). This allegation has been realigned with Manuscript #6 (Oncogene 2008) to discuss its associated allegations in one section.

<sup>166</sup> The PNAS 2008 paper is: Garzon R\*, Garofalo M\*, Martelli MP, Briesewitz R, Wang L, Fernandez-Cymering C, Volinia S, Liu CG, Schnittger S, Haferlach T, Liso A, Diverio D, Mancini M, Meloni G, Foa R, Martelli MF, Mecucci C, Croce CM, Falini B. "Distinctive microRNA signature of acute myeloid leukemia bearing cytoplasmic mutated nucleophosmin." PNAS. 2008 Mar 11;105(10):3945-50. doi: 10.1073/pnas.0800135105. Epub 2008 Feb 28. \*Co-first authors

<sup>167</sup> Ex. 660 - COMIC Figure Forensics-Garofalo\_FINAL, slides 12-14

<sup>168</sup> Ex. 638 - 20190912-Email Garofalo to RIO\_Response to Allegations

<sup>169</sup> Ex. 640 - GarafaloetalFig3



- b. The attachment “Garofalo Oncogene–PNAS U6”<sup>170</sup> is a written response to the allegation, which claims that Dr. Garofalo does not believe that the two U6 blots are the same and also states, “From what I recall, I did not perform the northern blot in Fig. 4C of the PNAS paper.”
  - c. The attachment “U6 Oncogene-PNAS.tif”<sup>171</sup> is a comparison between an enlarged image of Figure 4C of Garzon PNAS 2008 and an enlarged image of the purported original data for Figure 3B of Garofalo Oncogene 2008. This comparison is also included in the written response.<sup>172</sup> Dr. Garofalo points out what she believes to be differences between the two U6 images.
- 4) Adobe Photoshop forensic overlay shows that the 4 lanes in GarofaloFig3 are similar to the 4 lanes in the U6 panel in Figure 3B of Garofalo Oncogene 2008 (see slide 15).<sup>173</sup>
  - 5) Dr. Garzon, the co-first author on PNAS 2008, also responded to this allegation. On November 6, 2019, Dr. Garzon submitted a letter<sup>174</sup> and associated exhibits through his counsel, Mr. Paul Thaler (labeled as Exhibits 1-10). Dr. Garzon claimed that he found a limited number of electronic files containing raw data and provided the original source data for Figure 4C in PNAS 2008 in Exhibit 8<sup>175</sup> and Exhibit 10.<sup>176</sup>
    - a. Exhibit 8 contains the file named “north norm,”<sup>177</sup> which is included in COMIC Figure Forensics – Garofalo\_FINAL, as slide #16. The file includes an unlabeled scan of a full blot. Forensic analysis shows that lanes 1-4 of the scan, stretched as compared to the original, match the published U6 blot in Figure 4C of Garzon PNAS 2008 (see slide 18-19).<sup>178</sup>
    - b. Exhibit 10 is an email, dated September 14, 2007, to Dr. Garzon from Tiziana Palumbo, who was then a postdoctoral fellow in the Croce lab. The attached tif file is labeled “tizi mir155”<sup>179</sup> and is included in COMIC Figure Forensics – Garofalo\_FINAL, as slide #17. Forensic analysis shows that lanes 1-4 of the scanned gel, flipped and stretched from the original, match the published mirR-155 blot in Figure 4C of Garzon PNAS 2008 (see slide 18-19).<sup>180</sup>
  - 6) On November 6, 2019, Dr. Garzon provided a written response.<sup>181</sup> Dr. Garzon claimed he had no recollection of being involved with the editing or creating Figure 4C in Garzon PNAS 2008. Dr. Garzon claimed that at the time, he was no longer performing bench research, due to his clinical responsibilities, and instead was leading the research team, assigning tasks, writing the text for the PNAS 2008 manuscript, and submitting the paper to journals.
  - 7) In the COMIC interview on November 15, 2019, Dr. Garzon said he did not remember doing any figures for the Garzon PNAS 2008 paper and at the time he was seeing patients and making the transition out of the Croce lab.<sup>182</sup> He said he was the first author on the paper because he helped develop the idea for the research.<sup>183</sup> Dr. Garzon was unable to explain how the same image was used in Garzon PNAS 2008 and Garofalo Oncogene 2008, but said that since he was not a co-author on Garofalo Oncogene 2008, he would not have had access to any of the data in that paper. Further, since Dr. Garofalo was a co-first author on the Garzon PNAS 2008 paper, Dr. Garofalo would have had access to his Northern blot folder where the data was stored for Oncogene 2008.<sup>184</sup>

<sup>170</sup> Ex. 639 - Garofalo Oncogene-PNAS U6

<sup>171</sup> Ex. 641 - U6-Oncogene-PNAS

<sup>172</sup> Ex. 639 - Garofalo Oncogene-PNAS U6

<sup>173</sup> Ex. 660 - COMIC Figure Forensics-Garofalo\_FINAL, slide 15

<sup>174</sup> Ex. 675a- 2019-11-06 Dr. Garzon Pre-Interview Submission\_Redacted-Garofalo

<sup>175</sup> Ex. 685 - Exhibit 8 - PNAS 2008 Submission Files , see “north norm”

<sup>176</sup> Ex. 687 - Exhibit 10 - 2009-09-14 Palumbo Email to Garzon and Attachment

<sup>177</sup> Ex. 690 - “north norm”

<sup>178</sup> Ex. 660 - COMIC Figure Forensics-Garofalo\_FINAL, slides 16, 18-19

<sup>179</sup> Ex. 688 - Exhibit 10 attachment-tizi mir155

<sup>180</sup> Ex. 660 - COMIC Figure Forensics-Garofalo\_FINAL, slides 17-19

<sup>181</sup> Ex. 675a - 2019-11-06 Dr. Garzon Pre-Interview Submission\_Redacted-Garofalo, page 7

<sup>182</sup> Ex. 698a - 20191115 - COMIC Interview + errata – Garzon\_Redacted-Garofalo, p. 34, lines 4-12

<sup>183</sup> Ex. 698a - 20191115 - COMIC Interview + errata – Garzon\_Redacted-Garofalo, p.35, lines 18-21

<sup>184</sup> Ex. 698a - 20191115 - COMIC Interview + errata – Garzon\_Redacted-Garofalo, p. 38, lines 9-25 and p. 39 lines 1-4



- 8) In the COMIC interview on October 31, 2019, Dr. Garofalo said she did not perform the Northern blots for Figure 4C or any of the figures in PNAS 2008 and she believes that the U6 blots in Oncogene 2008 Figure 3B and the U6 blot PNAS 2008 Figure 4C are not the same. Dr. Garofalo then said that she performed the Western blots in Figure 2 in PNAS 2008 and gave Dr. Garzon the raw data, but said that the Northern blots were done by “other people” and not her.<sup>185</sup> Dr. Garofalo said that she made the figures for Oncogene 2008.<sup>186</sup> Dr. Garofalo said that she sent the data to her previous supervisor, Dr. Condorelli, who organized the figures.<sup>187</sup>
- 9) The correction published on January 4, 2021, did not address the allegation of the reuse of data in Figure 3B.

### **Respondent's Responsibility and Intent:**

Dr. Garofalo and Dr. Garzon both provided data related to Figure 3B in Oncogene 2008 and Figure 4C in PNAS 2008. Dr. Garofalo provided an unlabeled scan<sup>188</sup> of the U6 panel, although Dr. Garofalo was adamant that she did not perform the Northern blot experiments for the PNAS 2008 publication. Dr. Garofalo further claimed that the Western blot experiments that she did perform for PNAS 2008 were given to Dr. Garzon and any data for experiments she performed for Oncogene 2008 were given to Dr. Condorelli to make the figures. Dr. Garzon also provided data as Exhibits 8<sup>189, 190</sup> and 10<sup>191, 192</sup> with his written response, which included unlabeled scans of gels for miR-155 and U6. Forensic analysis shows that these gels were used in Figure 4C of Garzon PNAS 2008. The COMIC believes that this evidence weakens Dr. Garzon's explanations about his involvement and participation in Garzon PNAS 2008 as being limited to leading the team and writing/submitting the manuscript and supports his position as a co-first author on the publication. However, because both Drs. Garofalo and Garzon were involved in using the U6 image, the COMIC is unable to determine who did the U6 experiment or who was first to have, or use, the U6 image. Thus, without identifying who was responsible for the reuse of the data, a Research Misconduct finding cannot be proven.<sup>193</sup>

### **Committee Conclusion:**

By a preponderance of the evidence, the Committee finds by a vote of 2 in favor to 6 against, that the Respondent intentionally, knowingly, or recklessly falsified the Northern blot data in Oncogene 2008 and/or PNAS 2008, and this **does not** constitute Falsification as described in the Policy III. A and 42 C.F.R. § 93.103 (b).

(The PNAS 2008 publication does cite PHS support; Oncogene 2008 does not cite any PHS support).

### **Manuscript under review-Nature Medicine 2012 (1 Allegation)**

Garofalo M, Romano G, Di Leva G, Gerard Nuovo, Young-Jun Jeon, Apollinaire Ngankeu, Jin Sun, Francesca Lovat, Hansjuerg Alder, Gerolama Condorelli, Jeffrey A Engelman, Mayumi Ono, Jin Kyung Rho, Luciano Cascione, Stefano Volinia, Kenneth P Nephew & Carlo M Croce. EGFR and MET receptor tyrosine kinase-

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<sup>185</sup> Ex. 658 - 20191115 - COMIC Interview + errata - Garofalo, p.81, lines 10-15

<sup>186</sup> Ex. 658 - 20191031 - COMIC Interview + errata - Garofalo, p. 77, lines 11-23 and p. 78, lines 9-16

<sup>187</sup> Ex. 658 - 20191031 - COMIC Interview + errata - Garofalo, p. 85, lines 3-14

<sup>188</sup> Ex. 640 - GarofaloetalFig3

<sup>189</sup> Ex. 685- Exhibit 8 - PNAS 2008 Submission Files

<sup>190</sup> Ex. 690 - "north norm"

<sup>191</sup> Ex. 687 - Exhibit 10 - 2009-09-14 Palumbo Email to Garzon and Attachment

<sup>192</sup> Ex. 688 - Exhibit 10 attachment-tizi mir155

<sup>193</sup> Although there was no finding of Research Misconduct for Allegation #16, the COMIC concluded that the PNAS editor should be notified of the additional issues related to Figure 4C. Since PNAS 2008 was reviewed in a separate matter (DIO 7024), the notification to the editor will be handled by another coauthor.



altered microRNA expression induces tumorigenesis and gefitinib resistance in lung cancers. *Nature Medicine*. 2012;18(1):74-82. doi:10.1038/nm.2577 **Correction: 11/19/13**<sup>194,195</sup>

**Manuscript #7, Allegation #13** - Dr. Garofalo falsified Figure 1B, in which the same data were used in the shEGFR panel (lines miR-30c to miR-101) and the shMET panel (lines miR-548d to miR-203).

[Note: This allegation was amended in the Inquiry.]<sup>196</sup>

#### Finding of Fact:

- 1) Figure 1B is a dendrogram/heatmap representing the changes in miRNA expression in Calu-1 cells following knockdown of EGFR or MET.
- 2) The allegation from the Complainant, Dr. Sanders, claimed the same data were used for the shEGFR column (miR-30C through miR-101) and the shMET column (miR-548D through miR-218) in the dendrogram/heatmap presented in Figure 1B (see slide #21<sup>197</sup>).
- 3) Visual inspection of a side-by-side comparison of the dendrogram by lining up the sh-control (sh-Ctr) panels and sh-experimental (either shEGFR or shMET treated) shows that both the control and sh-experimental columns are identical, for shCtr/shEGFR panels between miR-30c to miR-101, and for the shCtr/shMET panels miR-548d to miR-203 (**not miR-218** as alleged) (see slide #21<sup>198</sup>).
- 4) The COMIC also noted that the first row of the shCTR panel associated with shMET appears to have been cropped showing only half of the row for miR-548d, at the very top of the panel (see the red arrow on slide #22<sup>199</sup>).
- 5) The COMIC received and reviewed the raw data from the OSU core facility.<sup>200, 201, 202</sup>
- 6) The correction that was published on November 19, 2013, did not involve the allegation being investigated here.
- 7) A section of the dendrogram/heatmap representing the changes in miRNA expression in Calu-1 cells following knockdown of EGFR or MET was also found as Figure 2 in both NIH grant applications U01 CA166905-01 and -01A1. The grant was funded from 7/2/2013 through 6/30/2018 and Dr. Garofalo was listed as a Postdoctoral fellow on both grant applications.

#### Respondents Response:

- 1) In a written response provided on April 12, 2019,<sup>203</sup> Dr. Garofalo wrote that she could not find the files used to generate the dendrograms in Figure 1B but that the original values were published in tables in Supplementary Figure 1A.<sup>204</sup> Dr. Garofalo stated that the conclusions from the figure in question were validated by other figures in the manuscript (Supplemental Figs. 7-10 and 12).
- 2) In the written response to the allegations, provided on April 2, 2019, Dr. Garofalo stated that the heatmaps/dendrograms in Figure 1B were generated by a bioinformatician.<sup>205</sup> The COMIC noted that the author contributions section of the paper indicates that author "H.A" (9<sup>th</sup> author- Hansjuerg Alder) performed the microarray experiments and analysis, but the author contributions section does not

<sup>194</sup> Ex. 497 - Correction-Garofalo et al *Nature Medicine* 2012

<sup>195</sup> The correction pertains only to Figure 1a and 6g.

<sup>196</sup> The original allegation claimed duplication of shMET column from miR-548D through miR-218. The CII reviewed the issue and has amended the allegation to duplication of columns from miR-548d through miR-203 for *both* the control (shCtr) and experimental (shEGFR/shMET) panels.

<sup>197</sup> Ex. 660 - COMIC Figure Forensics-Garofalo\_FINAL, slide 21

<sup>198</sup> Ex. 660 - COMIC Figure Forensics-Garofalo\_FINAL, slide 21

<sup>199</sup> Ex. 660 - COMIC Figure Forensics-Garofalo\_FINAL, slide 22

<sup>200</sup> Ex. 670 - 20191030-Email Core to RIO-Raw Data

<sup>201</sup> Ex. 671 - 11-12-09 Michela Calu v2.0 A.sdm-Result Data

<sup>202</sup> Ex. 672 - 11-12-09 Michela Calu v2.0 B.sdm-Result Data

<sup>203</sup> Ex. 510 - 201904012-Garofalo Response to Allegations

<sup>204</sup> Ex. 513 - Supplemental Figures-Garofalo et al *Nature Medicine* 2011, page 13

<sup>205</sup> Ex. 489 - 20190402-Garofalo Response to Allegations



- indicate who generated the figure from the experimental data.
- 3) In a written response to the CII Amendment provided on May 10, 2019, Dr. Garofalo wrote that Dr. Alder did not generate the figure in question.<sup>206</sup> Dr. Garofalo further stated that "*the heatmaps have been cropped in order to fit into the figure*" and only those miRNAs with changes greater than 1.5-fold (for EGFR) and 1.7-fold (for MET) are shown. Dr. Garofalo again wrote that the original values for the differentially expressed microRNAs were published in Supplementary Figure 1, which more accurately indicate the fold changes than the heatmaps.
  - 4) In the COMIC interview on October 31, 2019, Dr. Garofalo stated that she did not create the heatmap and confirmed that the original data behind the heatmap in Figure 1B was included as Tables 1 and 2 in Supplementary Fig 1A.<sup>207</sup> Dr. Garofalo said that there were three (3) co-first authors on the paper and she did not remember who was responsible for the questioned data.<sup>208</sup>
  - 5) In a written response provided on April 11, 2019, Dr. Croce wrote that he did not prepare the questioned figure and believed that "*it is impossible to falsify an image that has 20 data points (counting from miR 30c to miR 101 of figure 1b) with that which has 24 data points (counting from miR-548d to miR-218 of figure shMET)*".<sup>209</sup> Following its review of the allegation, the CII amended the allegation for both the control (shCtr) and experimental (shMET) panels, with the duplication between miR-548D through **miR-203** rather than miR-548d through **miR-218** as alleged.
  - 6) The COMIC reviewed the raw data and noted inconsistencies between the heatmap in Figure 1B and the raw data in Table 1 and 2 in Supplemental Fig. 1A. For example, the data for miR-30c, mir548D (shMET knockdown) appeared to have identical expression from the heatmap, but in Figure S1A (Table 1 and 2) these genes showed different values (see arrows on slide 23). The COMIC also noted the unusual scale in Figure 1B for the heatmap as 3, 2, 1, 0, -3, -2, -1 rather than 3, 2, 1, 0, -1, -2, -3 as it would be if it had been generated from a program. Thus, it appears that the heatmap was cropped and the scale was added in when Figure 1B was created.
  - 7) In the COMIC interview on November 19, 2019,<sup>210</sup> Dr. Croce agreed that the scale in Figure 1B looked incorrect and Dr. Croce agreed that someone did the heatmap and gave it to the first author, Dr. Garofalo, who must have made the figure.
  - 8) In the written response of May 10, 2019, Dr. Garofalo detailed a 2013 Alternative Resolution regarding other figures in Nature Medicine 2012 that were reviewed previously by OSU.<sup>211,212</sup> Dr. Garofalo wrote that in 2013, nine (9) allegations were received against the Nature Medicine 2012 paper but that only one (1) beta-actin panel was determined to be misplaced in Figure 1A. A correction was published in 2013.<sup>213</sup>

### Respondent's Responsibility and Intent:

Dr. Garofalo is listed as one of the co-first authors on the paper. In the COMIC interview,<sup>214</sup> Dr. Garofalo specifically remembered that she did not make the heatmap; that the heatmap only included certain microRNAs so the image had to be cropped; that the experiments had been done numerous times; and that a statistical analysis had been done to determine the fold change for the different microRNAs, with the averages presented in Supplemental Figure 1A, Tables 1 and 2. Dr. Garofalo also remembered that she was given the heatmap by the bioinformatician.<sup>215</sup> When Dr. Garofalo was asked during the COMIC interview about the errors of the scale

<sup>206</sup> Ex. 568 - response to amendment of the CII report

<sup>207</sup> Ex. 658 - 20191031 - COMIC Interview + errata - Garofalo, pp.54-55, 57

<sup>208</sup> Ex. 658 - 20191031 - COMIC Interview + errata - Garofalo, pp. 58, 69-75

<sup>209</sup> Ex. 500b - Croce Response to All\_page 4-8: see pages 7-8

<sup>210</sup> Ex. 710d - 20191119 - COMIC Interview + errata - Croce\_Redacted-Garofalo, p. 93, lines 1-12

<sup>211</sup> Ex. 569 - 20130828 - ORI\_Notification\_to\_OSU\_of\_final\_decision

<sup>212</sup> ORC reviewed the case files and the final determinations of the 2013 Alternative Resolution of the Nature Medicine 2012 publication and determined that the issue of potential data duplication in the heatmap of Figure 1B was not reviewed.

<sup>213</sup> Ex. 497 - Correction Garofalo et al Nature Medicine 2012

<sup>214</sup> Ex. 658 - 20191031 - COMIC Interview + errata - Garofalo, pp. 53-76

<sup>215</sup> Ex. 658 - 20191031 - COMIC Interview + errata - Garofalo, p. 58

in Figure 1B, Dr. Garofalo said she was sure she did not generate the scale.<sup>216</sup> When asked about the discrepancies between the raw data in Supplemental Figure 1A and the heatmap in Figure 1B, Dr. Garofalo stated that the raw data in Supplemental Figure 1 was correct and that the heatmap itself was only a visual representation and she implied that since the results are based on the supplemental data, the heatmap was less relevant.<sup>217</sup> Despite remembering these many details, Dr. Garofalo could not remember who cropped the heatmap, who prepared the figure, or who wrote the legend for the heatmap in Figure 1B.<sup>218</sup> Dr. Garofalo stated that there were three co-first authors and she did not know who was responsible. When further questioned, Dr. Garofalo said “*we cropped it, otherwise the, you know, we couldn't fit the heat maps in the figure*” and when asked who cropped it, she replied “*Yeah. Me or somebody else, or one of the coauthors or one of the authors, I don't remember.*”<sup>219</sup> Further, Dr. Garofalo also remembered that in 2013 when nine allegations were raised about Nature Medicine 2012, it was Dr. Garofalo who had to collect and provide the raw data for the figures to send to the journal.<sup>220</sup> When asked about the raw data for the heatmap, Dr. Garofalo answered that the raw data were not available, and that the only data she had were the data shown in the tables in Supplemental Figure 1.

Based on her responses, the COMIC believes that Dr. Garofalo was fully involved in the experiments presented in Figure 1B and Supplemental Figure 1 (Tables 1 and 2) in Nature Medicine 2012. The COMIC finds this to be obvious since Dr. Garofalo is the first listed author on the publication, she was tasked with providing the raw data to the journal in 2013 when a problem arose, and she clearly remembered many details about the experiments presented in Figure 1B. The COMIC does not find it credible that Dr. Garofalo, as the first co-author on the paper, would remember many specific details related to the experiments for Figure 1B and Supplemental Figure 1, yet be unable to recall those details about who was responsible for compiling Figure 1B or writing the figure legend.

Based on the testimony from Dr. Garofalo and the data recovered from the OSU core facility reviewed by the COMIC, the COMIC believes that Dr. Garofalo was provided .txt data files from the core facility that were then given to the bioinformatician to generate the heatmaps, and the heatmaps were then provided to Dr. Garofalo. The COMIC found that in her interview, Dr. Garofalo provided vague responses to obscure identifying who constructed Figure 1B. The COMIC believes that the evidence shows it is more likely than not that Dr. Garofalo was responsible for generating Figure 1B, which included a duplicated heatmap, an incorrect scale, and data that was not consistent with the mean data values found in Supplemental Figure 1A, Tables 1 and 2. The COMIC believes that Dr. Garofalo, as the first listed co-author on the paper who was most senior and involved in the experiments for Figure 1B, should have checked the heatmap for accuracy when the paper was submitted. Dr. Garofalo admitted knowing that the heatmap had been cropped and even a cursory review would have clearly shown only half of the row for miR-548d in the first row of the shCtr/shMET panel. The COMIC believes that Dr. Garofalo also should have compared the heatmap data to the raw data in Supplemental Tables 1 and 2 to ensure its accuracy prior to publication, which is consistent with the standard practices in the research community. The COMIC is very concerned that in 2013 Dr. Garofalo became aware of problems with several figures in the Nature Medicine paper, and at that time, she did not verify the accuracy of *all* the figures in the manuscript, including Figure 1B. The COMIC believes this shows a risk that falsified data were published in Nature Medicine 2012, and a disregard on the part of Dr. Garofalo for ensuring that all the published data were correct.

### Significance:

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<sup>216</sup> Ex. 658 - 20191031 - COMIC Interview + errata - Garofalo, p. 71

<sup>217</sup> Ex. 658 - 20191031 - COMIC Interview + errata - Garofalo, pp. 72-73

<sup>218</sup> Ex. 658 - 20191031 - COMIC Interview + errata - Garofalo, pp. 66-67

<sup>219</sup> Ex. 658 - 20191031 - COMIC Interview + errata - Garofalo, p. 69

<sup>220</sup> Ex. 658 - 20191031 - COMIC Interview + errata - Garofalo, p. 55



The COMIC finds that the heatmap in Figure 1B is inconsistent with the underlying raw data presented in Supplementary Figure 1A, and Figure 1B remains incorrect in the scientific literature. The COMIC believes that Dr. Garofalo was on notice in 2013 when many problems were raised regarding the data in Nature Medicine 2012, and she should have reviewed *all* of the figures for accuracy at that time. This Falsification that has remained in the scientific literature adds to the significance of the Falsification.

In summary, Dr. Garofalo admitted to knowing that the heatmap image had been cropped since the image only included certain microRNAs. As the first listed author on the paper and the author that handled compiling the data for the correction in 2013, the COMIC believes that Dr. Garofalo's behavior was inconsistent with how a typical researcher would handle a correction and a review of data in a published paper if concerns were raised about the paper. The COMIC believes that Dr. Garofalo was responsible to ensure the accuracy of the data included in Nature Medicine 2012 when it was submitted and did not properly execute her duties as first senior co-author. Further, in 2013 Dr. Garofalo was aware of the risk of falsified data being included in Nature Medicine 2012, and disregarded that risk to allow the falsified Figure 1B to continue to remain in the published literature. Therefore, the COMIC determined that Dr. Garofalo's reckless actions led to the Falsification of Figure 1B and the continued Falsification of the image in the published literature, and this represents reckless Research Misconduct.

#### **Committee Conclusion:**

By a preponderance of the evidence, the Committee finds by a vote of 8 in favor to 0 against, that the Respondent's reckless actions led to the falsification of the heatmap in Figure 1B in Nature Medicine 2012 and allowed the falsified Figure 1B to continue to remain in the published literature and this act constitutes falsification as described in the Policy III. A and 42 C.F.R. § 93.103 (b). A section of this image was also included as Figure 2 in U01 CA 166905-01 and -01A1, (This publication does cite PHS support.)

#### **Manuscript under review-Calore Int J Mol Sci (1 Allegation)**

Calore, F, Lovat, F and Garofalo, M. Non-Coding RNAs and Cancer. Int J Mol Sci. Aug 2013; 14(8): 17085–17110.

**Manuscript #8, Allegation #14** - Dr. Garofalo plagiarized sixteen (16) specific instances of text in Int J Mol 2013.

#### **Finding of Fact:**

- 1) Using a side-by-side comparison, the text that was alleged to be plagiarized was copied nearly verbatim (see slides 70-92).<sup>221</sup>
- 2) The COMIC highlighted all instances of alleged plagiarism within the publication.<sup>222</sup>
- 3) Using a side-by-side comparison, the questioned text in instances #4, #5, #11, #13, #14, #15 and #16 all reference the source from which the text was copied (see slides 80-81, 87, 89-92). However, the COMIC notes quotation marks for the verbatim or nearly verbatim copying of text were not used.<sup>223</sup>
- 4) Using a side-by-side comparison, instances #6, #8, #9, #12 (see slides 82, 84-85, 88) include a citation to the original finding and the citation is present in the source publication; instances #1, #2, and #3 do not have any citations (see slides 77-79); and instance #10 cites to publications that are not cited in the source paper from which the text is copied (see slide 86).<sup>224</sup>
- 5) Using a side-by-side comparison, instance #7 includes a citation to the original finding that is also cited in the source paper (see slide 83). The source paper is authored by members of the Croce laboratory.<sup>225</sup>

<sup>221</sup> Ex. 661 - COMIC Plagiarism Forensics - Garofalo, slides 70-92

<sup>222</sup> Ex. 662 - Marked- Calore et al IJMS 2013-

<sup>223</sup> Ex. 661 - COMIC Plagiarism Forensics - Garofalo, slides 80-81, 87, 89-92

<sup>224</sup> Ex. 661 - COMIC Plagiarism Forensics - Garofalo, slides 77-79, 82, 84-86, 88

<sup>225</sup> Ex. 661 - COMIC Plagiarism Forensics - Garofalo, slide 83



- 6) This manuscript is a review article, and the instances of Plagiarism are found throughout the article.
- 7) In the written response to the allegations, provided on April 2, 2019, Dr. Garofalo stated that she believed the first and second author mainly wrote the manuscript in question.<sup>226</sup>
- 8) Dr. Garofalo reiterated that the textual overlap was not intentional and that she had no training in Plagiarism while she was working in the Croce laboratory.

**Respondent's Response:**

Dr. Garofalo's statements regarding Plagiarism are provided above under [Respondent Responses Regarding Plagiarism](#).

Dr. Croce's statements regarding Plagiarism are provided above under [Witness Response](#).

**Respondent's Responsibility and Intent:**

The specific comments regarding Dr. Garofalo's responsibility and intent regarding Plagiarism are provided above under [Respondent's Responsibility and Intent](#) for M#1, A#1. For this Allegation #13, the COMIC identified sixteen (16) instances of alleged Plagiarism. For seven (7) of these instances (#4, #5, #11, #13, #14, #15 and #16) the proper citation to the source was included, but quotation marks to denote identical text were not present. The COMIC believes that while this is inappropriate, it is possible, though unlikely, that Dr. Garofalo may not have known how to properly attribute text that is copied verbatim. Regardless, even excluding these issues, there are nine (9) other instances (#1, #2, #3, #6, #7, #8, #9, #10 and #12) of copied text that are similar to the way in which text had been copied in the other manuscripts under review with Dr. Garofalo as the first author, which either do not include citations or include citations to the findings that are also included in the source paper. Thus, the COMIC believes that it is more likely than not that Dr. Garofalo, in a Research Scientist position when this paper was published, was responsible for the Plagiarism. The COMIC concludes that although this is a review article and the copied text appears to be background information, this article is one (1) of eight (8) manuscripts published over six (6) years with Dr. Garofalo as the first, or senior, author that all include similarly plagiarized text. Thus, the COMIC finds that this issue of Plagiarism is more serious in combination with all the other similar Plagiarism issues, and in totality, represents Research Misconduct.

**Committee Conclusion:**

By a preponderance of the evidence, the Committee finds by a vote of 8 in favor to 0 against, that the Respondent intentionally, knowingly, or recklessly copied nine (9) specific instances of text and this act constitutes Plagiarism as described in the Policy III. A.

(This publication does not cite any PHS support).

**Manuscript under Review- Jeon PNAS 2015 (1 Allegation)**

Jeon YJ, Middleton J, Kim T, Laganà A, Piovan C, Secchiero P, Nuovo GJ, Cui R, Joshi P, Romano G, Di Leva G, Lee BK, Sun HL, Kim Y, Fadda P, Alder H, Garofalo M, Croce CM. "A set of NF-κB-regulated microRNAs induces acquired TRAIL resistance in lung cancer." Proc Natl Acad Sci U S A. 2015 Jun 30;112(26):E3355-64. Epub 2015 Jun 15. **Corrected – 03/21/2017**

**Manuscript #9, Allegation #15** - Dr. Garofalo plagiarized sixteen (16) instances of text in Jeon et al., PNAS 2015.

**Finding of Fact:**

- 1) Using a side-by-side comparison, the text that was alleged to be plagiarized was copied nearly verbatim from various sources (see slides 93-113).<sup>227</sup>

<sup>226</sup> Ex. 489 - 20190402 Garofalo Response to Allegations

<sup>227</sup> Ex. 661 - COMIC Plagiarism Forensics - Garofalo, slides 93-113





- 2) The COMIC highlighted all instances of alleged plagiarism within the publication (any instances of "self-plagiarism" were specifically excluded).<sup>228</sup>
- 3) The plagiarized text was included primarily in the Introduction and Discussion sections with 3 instances (#8, #9, and #10) in the Results section.
- 4) Using a side-by-side comparison, instances #4 and #6-15 include one (1) copied sentence; instances #2 and #5 are two (2) copied sentences, instance #16 is four (4) copied sentences; and instance #1 is six (6) copied sentences (see slides 98-113).<sup>229</sup>
- 5) Instance #3 is "self-plagiarism" with a single sentence of text copied from Garofalo, et al., *Oncogene* (2008) 27, 3845–3855 (Manuscript #6), and was dismissed as not meeting the definition of Plagiarism.

6) [REDACTED]

7) [REDACTED]

8) [REDACTED]

9) [REDACTED]

10) [REDACTED] The correction was published on March 21, 2017.<sup>245</sup>

- 11) [REDACTED] the CII referred the matter to investigation of Dr. Garofalo's role in this alleged Plagiarism. The COMIC reviewed all the documentation obtained during the inquiry.
- 12) The COMIC notes that the correction was published on March 21, 2017, before Dr. Garofalo was made

<sup>228</sup> Ex. 665 - Marked- PNAS-2015-Jeon

<sup>229</sup> Ex. 661 - COMIC Plagiarism Forensics - Garofalo, slides 98-113

[REDACTED]

<sup>245</sup> Ex. 028 - Correction PNAS-2015- Jeon



aware of the allegations under review in the Inquiry and this Investigation.

- 13) The COMIC reviewed the correction from March 2017 and found that only six (6) of the sixteen (16) instances of Plagiarism under review in this Investigation were corrected (instances #1, #2, #3, #7, #13, and #14).

**Respondent's Response:**

- 1) In her interview with the CII on March 2, 2018, Dr. Garofalo stated that she believed that she wrote the PNAS 2015 paper. The PNAS publication cites under author contribution that "Y. J-J and MG wrote the paper."
- 2) In her interview with the CII on March 2, 2018, Dr. Garofalo stated at that time she did not believe that copying the questioned text was considered to be Plagiarism.<sup>246</sup>
- 3) In a written response to the CII Amendment provided on May 10, 2019,<sup>247</sup> Dr. Garofalo wrote that in 2013, some allegations had been raised regarding figures in Nature Medicine 2012 (Manuscript #7) and a corrective action plan was initiated to ensure the accuracy of Dr. Garofalo's future data.
- 4) Dr. Garofalo's statements regarding Plagiarism are provided above under [Respondent Responses Regarding Plagiarism](#).
- 5) Dr. Croce's statements regarding Plagiarism are provided above under [Witness Response](#).

**Respondent's Responsibility and Intent:**

The specific comments regarding Dr. Garofalo's responsibility and intent regarding Plagiarism are provided above under [Respondent's Responsibility and Intent](#) for M#1, A#1. Specifically, for Allegation #15, one instance (#3) was considered to be "self-plagiarism" and was dismissed by the COMIC as not falling under the definition of Research Misconduct. The remaining fifteen (15) instances represent eleven (11) instances of a single sentence copied from various sources, two (2) instances of two (2) copied sentences, one (1) instance of four (4) copied sentences; and one (1) instance of six (6) copied sentences. The COMIC finds there is a significant portion of text in the Introduction section that is copied.<sup>248</sup>

the COMIC believes that it is more likely than not that Dr. Garofalo, in a senior position in the Croce laboratory and as co-corresponding author on PNAS 2015, appears to have been responsible for incorporating the allegedly plagiarized text in the manuscript during the later revisions of the manuscript.

In addition, the COMIC is very concerned that Dr. Garofalo became aware of issues of Plagiarism with this paper in 2015, and a correction was published in March 2017. Only six (6) of the sixteen (16) instances had been corrected in 2017. The COMIC finds that it is unacceptable that a researcher would not check the entire paper for other Plagiarism, with software tools that were readily available at that time, to ensure that any other issues of Plagiarism would be identified. The COMIC finds this lack of care is inconsistent with how a typical researcher would behave. Further, since Dr. Garofalo described that potential allegations of Research Misconduct had been raised in 2013, before PNAS 2015 was published, the COMIC believes that in 2013 Dr. Garofalo had to have been aware of what constitutes Research Misconduct, defined as Falsification, Fabrication and Plagiarism. This weakens Dr. Garofalo's explanation that she did not understand what was considered Plagiarism until 2015. The COMIC believes that Dr. Garofalo's apparent lack of care to ensure her papers were correct make this allegation even more serious.

The COMIC concludes that this article is one (1) of eight (8) manuscripts published over six (6) years with Dr. Garofalo as the first, or senior, author that all include similarly plagiarized text. Thus, the COMIC finds that this issue of Plagiarism is more serious in combination with all the other similar Plagiarism issues, and with Dr. Garofalo's prior awareness of potential allegations, and in totality represents Research Misconduct.

<sup>246</sup> Ex. 119 - 20180302-CII Interview + errata – Garofalo, page 58, lines 8-20

<sup>247</sup> Ex. 568 - response to amendment of the CII report

<sup>248</sup> Ex. 665 - Marked- PNAS-2015-Jeon



**Committee Conclusion:**

By a preponderance of the evidence, the Committee finds by a vote of 8 in favor to 0 against that the Respondent intentionally, knowingly, or recklessly copied fifteen (15) instances of text and this act constitutes Plagiarism as described in the Policy III. A.

(This publication does not cite any support).

**Summary of Investigation Committee Conclusions**

As defined under the University's Policy and Procedures Concerning Research Misconduct, "Falsification" is "manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in research record." "Plagiarism" is "the appropriation of the ideas, processes, results, or words of another person, without giving appropriate credit." Further, a finding of Research Misconduct requires that there is a significant departure from accepted practices of the relevant research community, and the misconduct be committed intentionally, knowingly, or recklessly, and the allegation be proved by a "Preponderance of the Evidence" under the federal regulations.

Based on the Preponderance of the Evidence standard, the COMIC determined for thirteen (13) allegations reviewed in this Investigation, there is sufficient evidence to make findings of Research Misconduct for eleven(11) allegations (Allegations #1-8, 15) and that there is insufficient evidence to make a finding of Research Misconduct for two (2) allegations (Allegations 12 and #16). The COMIC determined that Dr. Garofalo committed Research Misconduct by deviating from the accepted practices for handling images and preparing figures and writing manuscripts, and that Dr. Garofalo intentionally, knowingly, and/or recklessly falsified research data and plagiarized text.

During the course of the Investigation, the COMIC revised certain allegations, based on evidence identified, which became part of the findings of Research Misconduct. A summary of the COMIC's final findings of Research Misconduct is below.

- 1) Dr. Garofalo intentionally, knowingly, and/or recklessly plagiarized text from various sources and included the plagiarized text in seven(7) published papers. Specifically, Dr. Garofalo plagiarized:
  - a) ten (10) specific instances of text in Manuscript #1, Cancer Cell 2009, Dec 8;16 (6):498-509;
  - b) eight (8) specific instances of text in Manuscript #2, Curr Mol Med. 2012, Jan; 12 (1): 27-33;
  - c) eleven (11) specific instances of text in Manuscript #3, PLoS One 2013, Jun 21; 8 (6): e67581;
  - d) nine (9) specific instances of text in Manuscript #4, Drug Resist Update 2013, Jul-Nov; 16 (3-5): 47-59;
  - e) three (3) specific instances of text Manuscript #5, Ann Rev of Pharmacology & Toxicology 2011, 51: 1, 25-43;
  - f) nine (9) specific instances of text in Manuscript #8, Int J Mol Sci. Aug 2013, 14(8): 17085–17110;
  - g) fifteen (15) instances of text in Manuscript #9, Proc Natl Acad Sci U S A. 2015, Jun 30; 112(26): E3355-64.
  
- 2) Dr. Garofalo intentionally, knowingly, and/or recklessly falsified Western blot images in Manuscript #1, Cancer Cell 2009, Dec 8;16(6):498-509, by
  - a) falsifying Figure 1G in Cancer Cell 2009 and/or Figure 1B in PLoS ONE 2008, 3(12):e4070, by differentially cropping the beta-actin panel in Figure 1G, Cancer Cell 2009 and using the data for an unrelated experiment in Figure 1B in PLoS ONE 2008 for both beta-actin, lanes 1-2 and Akt, lanes 2-3;



- b) falsifying Figure 5B and/or Figure 5E, in which the same data were used as the Akt tot panel and as the beta-actin panel in Figure 5B, and also used as the beta-actin panel in Figure 5E, but flipped vertically;
  - c) falsifying Figure 7D and/or Figure 7F, by differentially cropping four lanes (3-6) from raw data labeled as MET and using lanes 3-5 to represent Met in GTL16 cells in Figure 7F and using lanes 5-6 as MET in Calu-1 cells in Figure 7D.
- 3) Dr. Garofalo's reckless actions led to the falsification of a dendrogram/heatmap in Figure 1B in Nature Medicine 2010; 18(1):74-83 (Manuscript #7), by using the same data in the shCtr/shEGFR panels between miR-30c to miR-100, and the shCtr/shMET panels between miR548d to miR203, and allowed the falsified Figure 1B to continue to remain in the published literature after a correction was published in 2017. A section of the dendrogram/heatmap was also included as Figure 2 in NIH grant applications U01 CA166905-01 and -01A1.

### **Response to the Preliminary Report**

Dr. Garofalo was provided a copy of the Preliminary Investigation Report on April 15, 2021.<sup>249, 250, 251</sup> As per the Policy, Dr. Garofalo was given thirty (30) days to file a written response. On April 27, 2021, Dr. Garofalo requested an extension through her attorney Ms. Katherine Ferguson.<sup>252</sup> The requested extension was until June 21, 2021, and the justification for the extension was the number of findings and the seriousness of the allegations. Dr. Randy Moses approved the extension request on April 27, 2021.<sup>253, 254, 255</sup> On June 14, 2021, Dr. Garofalo requested an additional extension through her attorney Ms. Katherine Ferguson.<sup>256</sup> The requested extension was to ensure sufficient time to respond to each allegation and was to be the last extension request. Dr. Randy Moses approved the extension request on June 15, 2021, and the new and final deadline was set as July 21, 2021.<sup>257, 258</sup> Dr. Garofalo provided a response to the Preliminary Investigation

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<sup>249</sup> Ex. 771 - 02210415 - Preliminary Investigation Report - Garofalo

<sup>250</sup> Ex. 772 - 02210415 - Letter RIO to Garofalo - COMIC PR

<sup>251</sup> Ex. 773 - 20210416 Email RIO to Garofalo - PR to new address

<sup>252</sup> Ex. 780 - 20210427 -EMAIL Garofalo attorney to RIO RE extension request

<sup>253</sup> Ex. 781- 20210427 -EMAIL RIO to DO RE -CONFIDENTIAL\_ Extension Request

<sup>254</sup> Ex. 782 - 20210427 -EMAIL DO TO RIO Re\_ CONFIDENTIAL\_ Extension Request

<sup>255</sup> Ex. 783 - 20210427 -EMAIL RIO to Garofalo RE extension request and buckeye box access

<sup>256</sup> Ex. 814 - 20210614 - EMAIL Garofalo attorney to RIO -Re\_ Additional extension request

<sup>257</sup> Ex. 815 - 20210615 - EMAIL DO to RIO -Re Additional extension request

<sup>258</sup> Ex. 816 - 20210615 - EMIAL RIO to Garofalo -Re\_ Additional extension request

Report on July 21, 2021. <sup>259, 260, 261</sup> The COMIC carefully reviewed Dr. Garofalo's response <sup>262</sup> and the supporting documentation. <sup>263, 264, 265, 266, 267, 268, 269, 270, 271, 272, 273</sup>

In her response to the preliminary report, Dr. Garofalo contends that Allegations #1-4, 8, 12-13 are time barred pursuant to the OSU Policy and must be dismissed.<sup>274</sup> The justification Dr. Garofalo provided is that the subsequent use exception does not apply to these manuscripts because OSU's current Research Misconduct Policy and standard operating procedures would exclude these publications from the subsequent use exception. The COMIC notes that this proceeding was initiated in June of 2017, and therefore neither Exhibit B – The Policy (the University Research Misconduct Policy)<sup>275</sup> nor Exhibit D – The Operating Procedure (Six-Year Time Limitation & Subsequent Use SOP)<sup>276</sup> provided by Dr. Garofalo are applicable. This research misconduct case is executed to its completion under the policies, procedures, and laws in effect at its initiation, in June 2017, and not under the Policy and SOP instituted on March 1, 2021.

Dr. Garofalo also maintains that the conclusions of the COMIC in reference to several allegations of falsification, did not negate the possibility of honest error.<sup>277</sup> Per 42 CFR §93.106, the burden of proof of honest error resides with the respondent and the COMIC was not provided with sufficient evidence to support the burden of proof. Simply stating that the falsification resulted from honest error is not sufficient, and the COMIC found that the evidence actually weakened the possibility of honest error. As an example, Dr. Garofalo claimed honest error for the falsification in allegation #3,<sup>278</sup> where the same bands were re-used to represent three different experimental conditions. The raw data provided to the COMIC included un-dated films which do not provide sufficient evidence to determine when the experiments were completed.<sup>279</sup> The COMIC also concluded that the control raw data shows that the samples were not evenly loaded, which undermines honest error and provides potential justification for the falsification. In addition, the COMIC's forensic analysis provides evidence that bands in the figure were rotated 180° before being re-used, also suggesting intentional falsification rather than honest error.

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<sup>259</sup> Ex. 817 - 20210721 -EMAIL Garofalo attorney to RIO\_Re response to PR

<sup>260</sup> Ex. 818 - 20210721 -Cover letter to OSU for written response

<sup>261</sup> Ex. 830 - 20210721 -Michela Garofalo Response to COMIC

<sup>262</sup> Ex. 830 - 20210721 -Michela Garofalo Response to COMIC

<sup>263</sup> Ex. 819 - 20210721 -Exhibit A - The Report

<sup>264</sup> Ex. 820 – 20210721 -Exhibit B – The Policy

<sup>265</sup> Ex. 821 – 20210721 -Exhibit C – Condorelli Letter #1

<sup>266</sup> Ex. 822 – 20210721 -Exhibit D – The Operating Procedure

<sup>267</sup> Ex. 823 – 20210721 -Exhibit E – Cancer Cell-Garofalo et al

<sup>268</sup> Ex. 824 – 20210721 -Exhibit F – Condorelli Letter #2

<sup>269</sup> Ex. 825 – 20210721 -Exhibit G – Professor Guttman Correspondence

<sup>270</sup> Ex. 826 – 20210721 -Exhibit H – Condorelli Letter #3

<sup>271</sup> Ex. 827 – 20210721 -Exhibit I – Professors Insel and Assaraf Correspondence

<sup>272</sup> Ex. 828 – 20210721 -Exhibit J -Dr. Delihis Correspondence

<sup>273</sup> Ex. 829 – 20210721 -Exhibit K -Professor Daul Correspondence

<sup>274</sup> Ex. 830 - 20210721 -Michela Garofalo Response to COMIC

<sup>275</sup> Ex. 820 – 20210721 -Exhibit B – The Policy

<sup>276</sup> Ex. 822 – 20210721 -Exhibit D – The Operating Procedure

<sup>277</sup> Ex. 830 - 20210721 -Michela Garofalo Response to COMIC

<sup>278</sup> Ex. 830 - 20210721 -Michela Garofalo Response to COMIC

<sup>279</sup> Ex. 660 - COMIC Figure Forensics-Garofalo\_FINAL, slide 6



Dr. Garofalo provided new evidence to the COMIC in her response to the Preliminary Investigation Report.<sup>280, 281, 282, 283, 284, 285, 286, 287</sup> This new evidence was reviewed thoroughly, and the COMIC had several follow up questions for Dr. Garofalo and Dr. Condorelli regarding some of the exhibits provided. On August 6, 2021, memos were emailed to Dr. Garofalo<sup>288</sup> and Dr. Condorelli<sup>289</sup> on behalf of the COMIC. The memo to Dr. Garofalo asked for clarification regarding why the documents were not previously provided to the COMIC during the course of the four-year research misconduct proceedings, requested actual emails rather than screenshots of correspondence with journals, and informed Dr. Garofalo that we would be reaching out to Dr. Condorelli to confirm the source of several exhibits. The memo to Dr. Condorelli asked for clarification of Dr. Garofalo's role in Manuscript #6, Oncogene 2008, and to confirm whether she wrote the manuscript and was accepting responsibility for the plagiarism. The deadline for the response to the COMIC's questions was August 20, 2021, for both Dr. Garofalo and Dr. Condorelli. Both requested extensions,<sup>290, 291</sup> and were given a new deadline of September 10, 2021, to respond.<sup>292, 293</sup>

Dr. Garofalo and Dr. Condorelli responded to the COMICs questions on September 10, 2021.<sup>294, 295</sup> The COMIC carefully reviewed the response and met via Zoom on September 24, 2021, for discussion. Overall, the COMIC unanimously agreed that for the majority of issues neither Dr. Garofalo's response to the Preliminary Investigation Report, nor response to the memos sent on behalf of the COMIC on August 6, 2021, changed their conclusions, votes, or recommended actions. In fact, several of the responses from Dr. Garofalo further substantiated their decisions. One such instance involved the heatmap in Manuscript #7, Allegation 13. The heatmap was meant to be a visual representation of the raw data, which was included in Supplementary Figure 1A as the means of the fold change in microRNA expression. The data in Supplementary Figure 1A did not match the heat map and the differences were very obvious and should have been identified, even by a first author with "no bioinformatics skills, training, or knowledge".<sup>296</sup>

However, the COMIC did reconsider the conclusion for Allegation #12. Although the COMIC continues to consider the plagiarism in Manuscript #6 (Allegation #12) to be serious, the inclusion of the letter from Dr. Condorelli stating that Dr. Garofalo did not contribute to the writing of Oncogene 2008, raises doubt on whether the preponderance of the evidence standard is met to hold Dr. Garofalo responsible.<sup>297</sup> In her response received September 10, 2021, Dr. Condorelli confirmed that Dr. Garofalo did not write the manuscript and was included as first author because she performed the majority of the experiments.<sup>298</sup> Therefore, following a discussion of this issue, the COMIC re-voted and unanimously determined that the evidence was not sufficient

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<sup>280</sup> Ex. 821 - 20210721 -Exhibit C – Condorelli Letter #1

<sup>281</sup> Ex. 823 – 20210721 -Exhibit E – Cancer Cell-Garofalo et al

<sup>282</sup> Ex. 824 – 20210721 -Exhibit F – Condorelli Letter #2

<sup>283</sup> Ex. 825 - 20210721 -Exhibit G – Professor Guttman Correspondence

<sup>284</sup> Ex. 826 – 20210721 -Exhibit H – Condorelli Letter #3

<sup>285</sup> Ex. 827 – 20210721 -Exhibit I – Professors Insel and Assaraf Correspondence

<sup>286</sup> Ex. 828 - 20210721 -Exhibit J – Dr. Delihis Correspondence

<sup>287</sup> Ex. 829 – 20210721 -Exhibit K – Professor Daul Correspondence

<sup>288</sup> Ex. 834 – Memo Re Resp to Prelim Inv Rpt-Garofalo

<sup>289</sup> Ex. 835 – Memo Re Resp to Prelim Inv Rpt-Condorelli

<sup>290</sup> Ex. 838 -20210816 -EMAIL Garofalo to RIO -extension request

<sup>291</sup> Ex. 840 -20210821 -EMAIL Condorelli to RIO Re -extension request

<sup>292</sup> Ex. 839 -20210818 -EMAIL RIO to Garofalo RE ext req granted

<sup>293</sup> Ex. 841 -20210823 -EMAIL -RIO to Condorelli ext request

<sup>294</sup> Ex. 836 -20210910 -Response from Garofalo -M. Garofalo Response to COMIC Memorandum

<sup>295</sup> Ex. 837 -20210910 -Response prof Condorelli sept 10 2021

<sup>296</sup> Ex. 830 -Michela Garofalo Response to COMIC, page 16

<sup>297</sup> Ex. 821 -20210721 -Exhibit C – Condorelli Letter #1

<sup>298</sup> Ex. 837 -20210910 -Response prof Condorelli sept 10 2021

for a finding of research misconduct against Dr. Garofalo for plagiarism in Manuscript #6 (Allegation #12). The COMIC still requires Dr. Garofalo to inform the editor of the plagiarized text.

Dr. Garofalo also provided the COMIC with email correspondence from Dr. Garofalo to the editors of Manuscripts #2, #4-5, and #8 requesting publication of a corrigendum to add missed references to each manuscript.<sup>299, 300, 301, 302, 303</sup> Although the COMIC appreciates Dr. Garofalo's willingness to correct the scientific record, they do not think that sending one email to each editor requesting a corrigendum, without a response, represents adequate due diligence on the part of the respondent. The COMIC would like to clarify that for each manuscript that includes plagiarized text (manuscript #'s 1-6, 8-9), the current editor of the journal should be provided with a corrected version of the manuscript with the addition of each omitted citation and a statement that The Ohio State University determined that the manuscript contained plagiarized text.

Dr. Sanders was provided a copy of the Preliminary Investigation Report on April 15, 2021.<sup>304, 305, 306</sup> As per the Policy, he was given thirty (30) days to file a written response. On May 15, 2021, Dr. Sanders provided a response to the Preliminary Investigation Report.<sup>307, 308</sup> Dr. Sanders' responses to the Preliminary Investigation Report were carefully reviewed and all typographical errors identified by Dr. Sanders were corrected.

### **Recommended Actions**

Under the University Policy and Procedures Concerning Research Misconduct, Section IV.F.5, the Committee shall include recommended sanctions in cases where allegations of Research Misconduct are substantiated. Since Dr. Garofalo is no longer employed by The Ohio State University, possible sanctions are limited. Given the pattern and scope of the Research Misconduct findings against Dr. Garofalo, the COMIC recommends to the College of Medicine that the following sanctions be imposed.

- 1) Dr. Garofalo be permanently ineligible for rehire at The Ohio State University.
- 2) Dr. Garofalo be required to work with the institution and the other co-authors in contacting the following journals to process corrections for the following manuscripts. In the event that figures cannot be corrected with verified original research records, then retractions will be required. If corrections have already been published, it is required that the editor is notified of the additional issues with the manuscript.
  - a. Manuscript #1: Garofalo M, Di Leva G, Romano G, Nuovo G, Suh SS, Ngankeu A, Taccioli C, Pichiorri F, Alder H, Secchiero P, Gasparini P, Gonelli A, Costinean S, Acunzo M, Condorelli G, Croce CM. "miR-221&222 regulate TRAIL resistance and enhance tumorigenicity through PTEN and TIMP3 downregulation." *Cancer Cell*. 2009 Dec 8; 16 (6): 498-509.  
Correction of 10 instances of plagiarized text and Figures 1G, 5B, 5E, 7D, and 7F.

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<sup>299</sup> Ex. 842 – 20210910 -EMAIL copy of corresp between Garofalo and editor for mn#2

<sup>300</sup> Ex. 843 – 20210910 -EMAIL copy of corresp between Garofalo and editor for mn#4

<sup>301</sup> Ex. 844 – 20210910 -EMAIL copy of corresp between Garofalo and editor for mn#5

<sup>302</sup> Ex. 845 – 20210910 -EMAIL copy of corresp between Garofalo and editor for mn#8

<sup>303</sup> Ex. 846 – 20210910 -EMAIL copy2 of corresp between Garofalo and editor for mn#8Fwd\_ IJMS paper

<sup>304</sup> Ex. 771 - 20210415 - Preliminary Investigation Report - Garofalo

<sup>305</sup> Ex. 786 - 20210415 -EMAIL RIO to COMPLAINANT -CONFIDENTIAL -Preliminary Reports\_Redacted

<sup>306</sup> Ex. 787 - 20210415 -Letter RIO to Sanders – COMIC PR

<sup>307</sup> Ex. 795 - 20210516 -EMAIL Sanders to RIO RE\_Response to Preliminary Investigation Reports

<sup>308</sup> Ex. 798 - 20210516 -Sanders COMIC response\_Redacted-Garofalo



- b. Manuscript #2: Garofalo M, Quintavalle C, Romano G, Croce CM, Condorelli G. "miR221/222 in cancer: their role in tumor progression and response to therapy." *Curr Mol Med*. 2012 Jan; 12 (1): 27-33.  
Correction of 14 instances of plagiarized text.
- c. Manuscript #3: Garofalo M, Jeon YJ, Nuovo GJ, Middleton J, Secchiero P, Joshi P, Alder H, Nazaryan N, Di Leva G, Romano G, Crawford M, Nana-Sinkam P, Croce CM. "MiR-34a/c-Dependent PDGFR- $\alpha/\beta$  Downregulation Inhibits Tumorigenesis and Enhances TRAIL-Induced Apoptosis in Lung Cancer." *PLoS One*. 2013 Jun 21; 8 (6): e67581.  
The correction published on June 25, 2015, adequately addresses only six (6) of the eleven (11) instances of plagiarized text, therefore Dr. Garofalo is required to work with the co-authors to notify the editor of the additional five (5) instances of plagiarized text (#1, #3, #4, #6, and #9)
- d. Manuscript #4: Garofalo M, Croce CM. "MicroRNAs as therapeutic targets in chemoresistance" *Drug Resist Updat*. 2013 Jul-Nov; 16 (3-5): 47-59. Epub 2013 Jun 10.  
Correction of 9 instances of plagiarized text.
- e. Manuscript #5: Garofalo, M and Croce CM. "microRNAs: Master Regulators as Potential Therapeutics in Cancer." *Annual Review of Pharmacology and Toxicology* 2011 51:1, 25-43.  
Correction of 3 instances of plagiarized text.
- f. Manuscript #6: Garofalo M, Quintavalle C, Di Leva G, Zanca C, Romano G, Taccioli C, Liu CG, Croce CM, Condorelli G. "MicroRNA signatures of TRAIL resistance in human non-small cell lung cancer." *Oncogene*. 2008 Jun 19; 27 (27): 3845-55. Epub 2008 Feb 4.  
The correction published on January 4, 2021, did not address the 1 instance of plagiarized text or the reuse of data in Figure 3B. Dr. Garofalo is required to inform the editor of the additional issues with this manuscript.
- g. Manuscript #7: Garofalo M, Romano G, Di Leva G, Gerard Nuovo, Young-Jun Jeon, Apollinaire Ngankeu, Jin Sun, Francesca Lovat, Hansjuerg Alder, Gerolama Condorelli, Jeffrey A Engelman, Mayumi Ono, Jin Kyung Rho, Luciano Cascione, Stefano Volinia, Kenneth P Nephew & Carlo M Croce. EGFR and MET receptor tyrosine kinase-altered microRNA expression induces tumorigenesis and gefitinib resistance in lung cancers. *Nature Medicine*. 2012;18(1):74-82.  
The correction that was published on November 19, 2013, did not involve address the allegation regarding Figure 1B. Dr. Garofalo is required to inform the editor that there is another issue in the manuscript.
- h. Manuscript #8: Calore, F, Lovat, F and Garofalo, M. Non-Coding RNAs and Cancer. *Int J Mol Sci*. Aug 2013; 14(8): 17085–17110.  
Correction of 9 specific instances of plagiarized text.
- i. Manuscript #9: Jeon YJ, Middleton J, Kim T, Laganà A, Piovan C, Secchiero P, Nuovo GJ, Cui R, Joshi P, Romano G, Di Leva G, Lee BK, Sun HL, Kim Y, Fadda P, Alder H, Garofalo M, Croce CM. "A set of NF- $\kappa$ B-regulated microRNAs induces acquired TRAIL resistance in lung cancer." *Proc Natl Acad Sci U S A*. 2015 Jun 30;112(26):E3355-64.  
The correction that was published in March 2017 addressed only six (6) of the sixteen (16) instances of Plagiarism under review in this Investigation (instances #1, #2, #3, #7, #13, and #14). Dr. Garofalo is required to inform the editor of the additional ten (10) instances of plagiarized text within the manuscript (#4-6, 8-12, and 15-16).



### Previous Corrections/Retractions

Four of the nine manuscripts under review have been corrected (Manuscripts #3, #6, #7 and #9).

Manuscript #3: Garofalo M, Jeon YJ, Nuovo GJ, Middleton J, Secchiero P, Joshi P, Alder H, Nazaryan N, Di Leva G, Romano G, Crawford M, Nana-Sinkam P, Croce CM. "MiR-34a/c-Dependent PDGFR- $\alpha/\beta$  Downregulation Inhibits Tumorigenesis and Enhances TRAIL-Induced Apoptosis in Lung Cancer." *PLoS One*. 2013 Jun 21; 8 (6): e67581. **Correction-06/25/2015**<sup>309</sup>

Manuscript #6 Garofalo M, Quintavalle C, Di Leva G, Zanca C, Romano G, Taccioli C, Liu CG, Croce CM, Condorelli G. "MicroRNA signatures of TRAIL resistance in human non-small cell lung cancer." *Oncogene*. 2008 Jun 19; 27 (27): 3845-55. Epub 2008 Feb 4 **Correction: 01/04/2021**  
Oncogene 2008 was corrected for Figures 4C and 7A and not for the allegations under review here.

Manuscript #7: Garofalo M, Romano G, Di Leva G, Gerard Nuovo, Young-Jun Jeon, Apollinaire Ngankeu, Jin Sun, Francesca Lovat, Hansjuerg Alder, Gerolama Condorelli, Jeffrey A Engelman, Mayumi Ono, Jin Kyung Rho, Luciano Cascione, Stefano Volinia, Kenneth P Nephew & Carlo M Croce. EGFR and MET receptor tyrosine kinase-altered microRNA expression induces tumorigenesis and gefitinib resistance in lung cancers. *Nature Medicine*. 2012;18(1):74-82. doi:10.1038/nm.2577. **Correction: 11/19/13**<sup>310</sup>  
Nature Medicine 2012 was corrected for the beta-actin loading control in Figure 1a and the splice in 6g and not for the issue under review here.

Manuscript #9: Jeon YJ, Middleton J, Kim T, Laganà A, Piovan C, Secchiero P, Nuovo GJ, Cui R, Joshi P, Romano G, Di Leva G, Lee BK, Sun HL, Kim Y, Fadda P, Alder H, Garofalo M, Croce CM. "A set of NF- $\kappa$ B-regulated microRNAs induces acquired TRAIL resistance in lung cancer." *Proc Natl Acad Sci U S A*. 2015 Jun 30;112(26):E3355-64. Epub 2015 Jun 15. **Corrected – 03/21/2017**<sup>311</sup>

### Length of Proceedings

This Research Misconduct proceeding was handled along with another related matter (DIO 6899) and has taken longer than the regulatory allotted one hundred and twenty (120) days to complete due to the extensive nature and scope of the allegations, the large number of manuscripts involved each containing many questioned figures, the number of witnesses involved, and the COVID-19 pandemic. The Ohio State University Office of

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<sup>309</sup> Ex. 020 - Correction-PLOS 2013 Garofalo et al.

<sup>310</sup> Ex. 497 - Correction Garofalo et al Nature Medicine 2012

<sup>311</sup> Ex. 028 - Correction PNAS-2015- Jeon



Research Compliance did obtain all necessary and appropriate extensions to the deadline from the Office of Research Integrity during this process.<sup>312, 313, 314, 315, 316, 317, 318, 319, 320, 321, 322, 323, 324, 325, 326, 327, 328, 329, 330, 331, 332</sup>

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- <sup>312</sup> Ex. 743 - 20191112 - ORI Extension Request\_Redacted
  - <sup>313</sup> Ex. 744 - 20191112 - Email RIO to ORI - Extension Request\_Redacted
  - <sup>314</sup> Ex. 745 - 20191113 - Email ORI to RIO - Extension Granted\_Redacted
  - <sup>315</sup> Ex. 746 - 20200311 - ORI Extension Request\_Redacted
  - <sup>316</sup> Ex. 747 - 20200311 - Email RIO to ORI - Extension Request\_Redacted
  - <sup>317</sup> Ex. 748 - 20200311 - Email ORI to RIO - Extension Granted\_Redacted
  - <sup>318</sup> Ex. 749 - 20200709 - ORI Extension Request\_Redacted
  - <sup>319</sup> Ex. 750 - 20200709 - Email RIO to ORI - Extension Request\_Redacted
  - <sup>320</sup> Ex. 751 - 20200709 - Email ORI to RIO - Extension Granted\_Redacted
  - <sup>321</sup> Ex. 752 - 20201019 - ORI Extension Request\_Redacted
  - <sup>322</sup> Ex. 753 - 20201019 - Email RIO to ORI - Extension Request\_Redacted
  - <sup>323</sup> Ex. 754 - 20201019 - Email ORI to RIO - Extension Granted\_Redacted
  - <sup>324</sup> Ex. 762 - 20210212 - ORI Extension Request\_Redacted
  - <sup>325</sup> Ex. 763 - 20210212 - Email RIO to ORI - Extension Request\_Redacted
  - <sup>326</sup> Ex. 764 - 20210216 - Email ORI to RIO - Extension Granted\_Redacted
  - <sup>327</sup> Ex. 811 - 20210615 - ORI Extension Request\_Redacted -Garofalo
  - <sup>328</sup> Ex. 812 - 20210615 - Email RIO to ORI - Extension Request\_Redacted
  - <sup>329</sup> Ex. 813 - 20210615 - Email ORI to RIO - Extension Granted\_Redacted
  - <sup>330</sup> Ex. 831 -20210915 -ORI Extension Request\_Redacted
  - <sup>331</sup> Ex. 832 -20210915 -EMAIL RIO to ORI -Extension Request\_Redacted
  - <sup>332</sup> Ex. 833 -20210915 -EMAIL ORI to RIO -Extension Granted\_Redacted





**Appendix**

**Complainant**

Dr. David Sanders, Purdue University, Associate Professor, Department of Biological Sciences

**Respondent**

Michela Garofalo, Ph.D.

Former Position: Visiting Scholar, Post-Doctoral Researcher, Research Scientist, OSU

Current Position: Junior Group Leader, Cancer Research, UK Manchester Institute, The University of Manchester, Manchester, England

**Respondent or Complainant Counsel**

Counsel to David Sanders: William Nolan, Esq. Barnes and Thornburg LLP

Counsel to Michela Garofalo: Katherine Connor Ferguson, Kooperman Mentel Ferguson Yaros

**Known PHS Support**

The questioned publications cited the following support from:

- U.S. Public Health Service (PHS), specifically National Cancer Institute (NCI), National Institutes of Health (NIH) as follows:

Manuscript #	Allegation #	PHS Support
1	1-4	No
2	5	No
3	6	<b>Yes – NCI CA152758</b>
4	7	No
5	8	No funding cited
6	12	No
7	13	<b>Yes – NCI CA113001</b>
8	14	No
9	15	No funding cited
10	16	<b>Yes – NCI P01CA76259 and P01CA81534</b>

**Committee Members**

- Arthur Burghes, Ph.D. (**Chair**) Professor, Department of Biological Chemistry and Pharmacology, College of Medicine
- Brandon Biesiadecki, Ph.D., Associate Professor, Department of Physiology & Cell Biology, College of Medicine
- Jonathan Davis, Ph.D., Professor, Department of Physiology and Cell Biology, College of Medicine
- Jill A. Rafael-Fortney, Ph.D., Professor, Department of Physiology & Cell Biology, Biological Chemistry & Pharmacology, College of Medicine
- Yutong Zhao, M.D., Ph.D., Professor, Department of Physiology and Cell Biology, College of Medicine
- Thomas Hund, Ph.D. (**non-COM representative**), Professor, Department of Biomedical Engineering, College of Engineering
- Loren Wold, Ph.D. (**non-COM representative**), Professor, Colleges of Nursing and Medicine (Physiology and Cell Biology)
- Colleen Rupp (**COM HR representative**), Senior Employee and Labor Relations Consultant, Wexner Medical Center Human Resources



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Courtney D. Mankowski, Former Associate Director and RIO, Office of Research Compliance  
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Julia Behnfeldt, Ph.D., Former OSU RIO, Associate Director, Office of Research Compliance  
Linda Neidhardt, Program Director, Office of Research Compliance

**OSU Office of Legal Affairs Staff**

Emily Schriver, Former Assistant Vice President and Senior Associate General Counsel, Office of Legal Affairs  
Brandon Lester, Associate General Counsel, Office of Legal Affairs

**Correspondence and Documentary Evidence**

20191202 - Email Garofalo to RIO<sup>333</sup>

20190523-Email RIO to Garofalo\_Appeal extension<sup>334</sup>

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<sup>333</sup> Ex. 673 - 20191202 - Email Garofalo to RIO

<sup>334</sup> Ex. 607 – 20190523-Email RIO to Garofalo\_Appeal extension