

BiDil, Clinical Trials and the Popular Press: An Exploration of Newspaper Coverage

Simrat Harry and Timothy Caulfield^{1*}

I. INTRODUCTION

News about biotechnology is everywhere – on the web, in magazines, on TV and in newspapers.¹ But, in many ways, the popular press coverage of biotechnology has been less than ideal.² Studies examining the quality of pharmaceutical coverage, for example, have found “substantial shortcomings in journalistic practices”.³ Coverage is often overly positive, superficial, and omits relevant information on such things as side effects and the limitations of the relevant study.⁴ This positive spin may result in the “hyping” of new technologies and drugs,⁵ thus potentially misleading both the public and the health care community.

BiDil, a combination heart failure medication, offers a fascinating case study in which to assess the quality of media coverage. Often considered the first “race-based” drug approved by the Food and Drug Administration (FDA), it generated a great deal of press coverage in both the scientific and lay media. In this paper, we build on our previous analysis of how the press covered the issue of race⁶ by exploring the degree to which the articles provided a balanced view of the efficacy and success of the relevant clinical trials. Specifically, we look at the degree to which the popular press provided information about both the strengths and weaknesses of the drug. Were both positive and negative attributes enumerated?

II. METHODS

Sample newspaper articles were collected using a search in the US news, major newspapers category of the

Lexis-Nexis database. The search term “BiDil” yielded 167 articles in total, of which 105 were accepted for inclusion. The accepted articles were from 28 major American newspapers, ranging in date from 05/03/2001 to 05/23/2007. A coding frame was developed based on a review of the relevant literature and a preliminary review of articles. The coding frame consisted of a series of questions with standardized categorical responses. The questions were on topics such as listed benefits of the drug, side effects and contraindications, as well as strengths and weaknesses of the clinical trials. One coder independently coded all the articles. A selection consisting of 10% of the articles was randomly selected to assess inter-coder reliability and was completed by a second coder. Inter-coder reliability was calculated using Cohen’s Kappa, with scores ranging from good to excellent.

III. RESULTS

The clinical trials and controversy

What did we find? For example, how did the media handle the controversy that emerged around the BiDil clinical trials? As background, it is important to note that many believe that the research surrounding BiDil has been less than ideal. The results of the first clinical trial, called the Vasodilator Heart Failure Trial (V-HeFT I), were deemed unconvincing by the relevant regulatory body, the US Food and Drug Administration’s (FDA) Cardiovascular and Renal Drug Advisory Committee.⁷ In response to the rejection, the researchers reexamined the data from V-HeFT I, finding some evidence the drug was



effective in an African-American subgroup.⁸ As a result, another set of trials (called A-HeFT) was undertaken to assess the drug efficacy in 1,050 self-reported African-American subjects. This trial found that BiDil significantly decreased mortality and hospitalization.⁹

While the A-HeFT clinical trial appeared to be a success – indeed, it led to the 2005 FDA approval of BiDil as a drug for a specific racially defined population¹⁰ – many commentators felt there were serious weaknesses with the research.¹¹ While critics accept BiDil is effective in treating heart failure, they contend the results of the research do not support the claim that the drug is only or more effective in African Americans.¹² Jonathan Kahn, for example, suggests that “[t]he medical evidence from A-Heft supports no claims regarding racial variation in response.”¹³

While other commentators have disagreed with the negative characterization of the BiDil trials,¹⁴ there seems little doubt that different perspectives on the strength of the research exist in the academic literature. As such, the popular press has been criticized for not reflecting this controversy.¹⁵

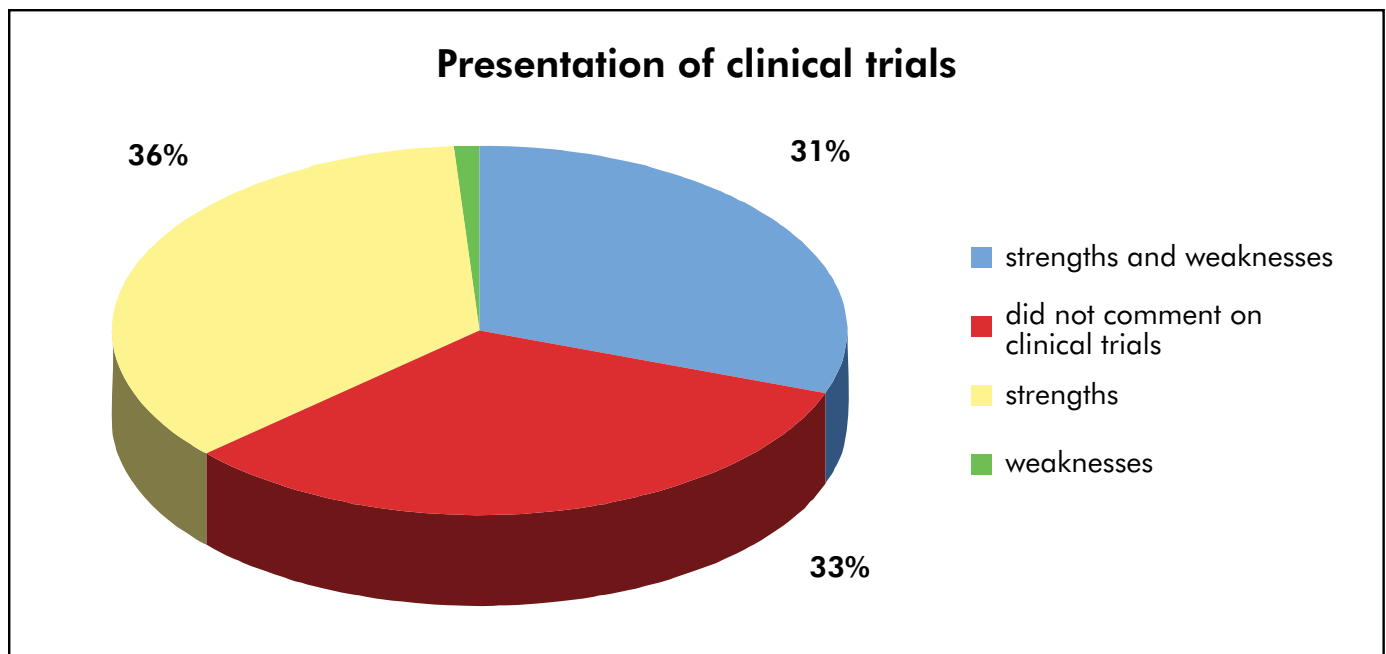
These criticisms are consistent with the results of our media analysis [See Chart I]. Only 32 of the 104 articles provided a balanced view of the clinical trials, reporting both strengths and weakness. Many of the

articles (34/104, 33%) failed to report either strengths or weaknesses, despite the controversy generated in the scientific media. Thirty-six percent (37) reported only strengths. In contrast, two articles referred to only the limits of the clinical trials.

Our results are consistent with other work on media reporting which has found, for example, that newspaper articles reporting on scientific and medical journal articles often attribute too much certainty to research findings, or make premature representations of findings as breakthroughs.¹⁶ Additionally the popular media may give incomplete or inaccurate information on clinical trials.¹⁷ For example, one study found only 15% of journal and newspaper articles discussed costs or risks associated with the research, while the majority (97%) discussed the likelihood of benefits of the research.¹⁸

Financial considerations and the clinical trials

Another controversy associated with BiDil is that financial considerations were a major driver underlying the development of BiDil as a race-based drug.¹⁹ In this view, the drug developer, NitroMed, undertook the race-based clinical trial (A-HeFT) in an effort to save the medication after the initial FDA rejection. Kahn has concluded thus: “Race apparently became relevant only when it offered a means to revive the commercial prospects of BiDil.”²⁰ In addition, there is



some speculation that the second trial, A-Heft, would have passed FDA approval without the accompaniment of a race-based claim. However, in that case, the patent would lapse in 2007 rather than 2020.²¹ While this was a major theme in a number of the relevant academic articles, the majority of newspaper articles did not mention the economic factors, which influenced the testing of the drugs. Our research found that out of 104 articles, only 25 (24%) mentioned economic factors underlying the race-based clinical trials.

Omissions in pharmaceutical reporting

The failure to report the negative aspects of a drug, including side effects and contraindications, is one of the most frequent omissions in news reports about pharmaceuticals.²² Canadian and US studies have found most articles take an overly positive view of medications by reporting on the benefits while downplaying the negative aspects.²³

Our examination of newspaper articles on BiDil found the majority did not discuss potential side effects, while potential benefits were frequently mentioned.

Our examination of newspaper articles on BiDil found the majority did not discuss potential side effects, while potential benefits were frequently mentioned. Only 4 articles out of 104 (4%) mentioned potential side effects, while over half of the articles (54 or 52%) mentioned at least one benefit, with many mentioning more than one. Of the articles reporting benefits, 50% (27/54) claimed BiDil was the first step towards decreasing health disparities experienced by African Americans. For example, Vanessa Northington Gamble, the Director of the Tuskegee University National Center for Bioethics in Research and Health Care, was quoted as saying “Race-based drugs can help overcome some of the racial inequalities in health care” in the article titled “Prejudicial treatment.”²⁴ Twenty-eight percent of articles claimed BiDil would improve the quality of life of heart failure patients. When improved quality of life was listed as a benefit, the article often conveyed personal experiences. For example, it was reported

that one patient who previously had difficulty walking short distances “has the energy to throw a baseball with his 10-year-old son and is looking forward to becoming well enough to return to work one day.”²⁵ Of the articles mentioning benefits, 46% referred to BiDil as the first step towards personalized medicine. In an article in the *Boston Globe* Christopher Rowland states: “[BiDil] represented a rudimentary first step toward the future of medicine, which scientists say will feature pharmaceuticals genetically tailored for individual racial groups and other sub-populations.”²⁶

III. THE VALUE OF BALANCED COVERAGE

Given the space and time constraints imposed on newspaper journalists, it is naïve to expect a comprehensive analysis of new medications. But the failure to provide a balanced perspective could compromise public understanding and expectations associated with new drugs.²⁷ There is at least some evidence that media influences the opinions and daily health decisions of the lay public.²⁸ A large percentage of Americans, for example, claim medical and health news helps them to lead a healthy life.²⁹ Health news reports also affect the interactions between health care providers and patients,³⁰ and may influence the treatments offered by health care providers.³¹ A study looking at the different ways in which study outcomes were reported found that the method of reporting trial results and the completeness of information influence physician willingness to prescribe medication.³² Of course, positive media coverage may also help the commercial success of a medication.³³

The story of BiDil is complex, requiring an understanding of pharmacology, genetics, race, commerce and how these various factors came together to create the first race-based drug. It appears that while the academic literature undertook a critical analysis of the drug and its development, the lay press offered more superficial coverage. In general, the lay press avoided reporting on the controversy surrounding the clinical trials and the financial and patent considerations underlying drug development. In addition, the lay press frequently emphasized benefits and neglected to report on things like side effects. Given the influence yielded by the popular press, it seems essential to explore ways in which a more balanced perspective can be presented.



Endnotes

- * Timothy Caulfield is a Canada Research Chair in Health Law and Policy; Senior Health Scholar, Alberta Heritage Foundation for Medical Research; Professor, Faculty of Law and School of Public Health; and Research Director, Health Law Institute, University of Alberta. Simrat Harry is a student researcher at the Health Law Institute and currently enrolled in her third year of law at the University of Alberta. We would like to thank the Advanced Food and Material Network and Genome Alberta for funding support, and Jonathan Kahn, Tania Bubela and Victor Alfonso for their insight and assistance.
- 1 See generally Toby A. Ten Eyck & Melissa Williment, "The National Media and Things Genetic: Coverage in the *New York Times* (1971-2001) and the *Washington Post* (1977-2001)" (2003) 25 *Science Communication* 129; Dorothy Nelkin, "Molecular metaphors: the gene in popular discourse" *Nature Reviews Genetics* 2:7 (July 2001) 555; Timothy Caulfield, "Popular Media, Biotechnology, and the 'Cycle of Hype'" (2005) 5 *Houston Journal of Health Law & Policy* 213.
 - 2 Mathew C. Nisbet & Bruce V. Lewenstein, "Biotechnology and the American Media: The Policy Process and the Elite Press, 1970 to 1999" (2002) 23 *Science Communication* 359 at 376.
 - 3 Ray Moynihan *et al.*, "Coverage By the News Media of the Benefits and Risks of Medications" (2000) 342 *New Eng. J. Med.* 1645 at 1645.
 - 4 *Ibid.*
 - 5 Timothy Caulfield, "The Media, Marketing and Genetic Services" in Colleen M. Flood, ed., *Just Medicare: What's In, What's Out, How We Decide* (Toronto: University of Toronto Press, 2006) 379.
 - 6 See Timothy Caulfield & Simrat Harry, "Popular Representations of Race: The News Coverage of BiDil" (2008) 36 *J.L. Med. & Ethics* 485.
 - 7 Michael D. Ruel, "Using Race in Clinical Research to Develop Tailored Medications: Is the FDA Encouraging Discrimination or Eliminating Traditional Disparities in Health Care for African Americans?" (2006) 27 *J. Legal Med.* 225 at 226.
 - 8 *Ibid.* at 228.
 - 9 Jay N. Cohn *et al.*, "Isosorbide Dinitrate and Hydralazine in a Fixed-Dose Combination Produces Further Regression of Left Ventricular Remodeling in a Well-Treated Black Population With Heart Failure: Results From A-Heft" (2007) 13 *Journal of Cardiac Failure* 331 at 333.
 - 10 *Supra* note 7 at 228.
 - 11 Kirsten Bibbins-Domingo & Alicia Fernandez, "BiDil for Heart Failure in Black Patients: Implications of the U.S. Food and Drug Administration Approval" (2007) 146 *Annals of Internal Medicine* 52. See also George Ellison, "Medicine in black and white: BiDil: race and the limits of evidence-based medicine" (2006) 3 *Significance* 118. See also Patricia O'Malley, "Ethnic Pharmacology: Science, Research, Race, and Market Share" (2005) 19 *Clinical Nurse Specialist* 291.
 - 12 Ellison, *ibid.* at 120.
 - 13 Jonathan Khan, "Race, Pharmacogenomics, and Marketing: Putting BiDil in Context" (2006) 6 *American Journal of Bioethics* W1 at W1.
 - 14 See e.g. Gary Puckrein, "BiDil: From Another Vantage Point" (2006) 25 *Health Affairs* W368; and Robert Temple & Norman L. Stockbridge, "BiDil for Heart Failure in Black Patients: The U.S. Food and Drug Administration Perspective" (2007) 146 *Annals of Internal Medicine* 57.
 - 15 Pamela Sankar & Jonathan Kahn, "BiDil: Race Medicine Or Race Marketing?" (2005) *Health Affairs* W5-455 at W5-460: some articles "implied that BiDil alone rather than BiDil in conjunction with established standard therapies, produced the trial's dramatic results."
 - 16 Christopher Bartlett, Jonathan Sterne & Matthias Egger, "What is newsworthy? Longitudinal study of the reporting of medical research in two British newspapers" (2002) 325 *British Medical Journal* 81.
 - 17 *Ibid.*
 - 18 Tania M. Bubela & Timothy A. Caulfield, "Do the print media 'hype' genetic research? A comparison of newspaper stories and peer-reviewed research papers" (2004) 170 *Canadian Medical Association Journal* 1399.
 - 19 Howard Brody & Linda M. Hunt, "BiDil: Assessing a Race-Based Pharmaceutical" (2006) 4 *Annals of Family Medicine* 556 at 558.
 - 20 *Supra* note 15 at W5-457. See also George T.H. Ellison *et al.*, "Flaws in the U.S. Food and Drug Administration's Rationale for Supporting the Development and Approval of BiDil as a Treatment for Heart Failure Only in Black Patients" (2008) 36 *J.L. Med. & Ethics* 449.
 - 21 *Supra* note 13.



- 22 Paul M. Wilson *et al.*, "Deconstructing media coverage of trastuzumab (Herceptin): an analysis of national newspaper coverage" (2008) 101 *Journal of the Royal Society of Medicine* 125 at 131.
- 23 *Supra* note 3 at 1649. See generally Alan Cassels *et al.*, "Drugs in the news: an analysis of Canadian newspaper coverage of new prescription drugs" (2003) 168 *Canadian Medical Association Journal* 1113. These studies are exemplified by the media coverage of Norplant, a contraceptive that was on the American market from 1991 to 2002 before being withdrawn. See e.g. Vikki A. Entwistle, Ian S. Watt & Fiona Johnson, "The case of Norplant as an example of media coverage over the life of a new health technology" (2000) 355 *Lancet* 1633 at 1633. In general, the researchers found media coverage in the early stages of the drug to be "uncritical about the product itself."
- 24 Stuart Laidlaw, "Prejudicial treatment" *Toronto Star* (28 April 2006) D1.
- 25 Denise Gellene, "Heart Pill Intended Only for Blacks Sparks Debate" *Los Angeles Times* (16 June 2005) C1.
- 26 Christopher Rowland, "Panel backs drug for blacks BiDil heart treatment is 1st aimed at specific race; FDA expected to give ok" *Boston Globe* (17 June 2005) E1.
- 27 The relationship of media to public perceptions is a complex issue beyond the scope of this short report. See generally Benjamin R. Bates, "Public culture and public understanding of genetics: a focus group study" (2005) 14 *Public Understanding of Science* 47.
- 28 Felicia E. Mebane, "The importance of news media in pharmaceutical risk communication: proceedings of a workshop" (2005) 14 *Pharmacoepidemiology and Drug Safety* 297 at 297.
- 29 *Ibid.*
- 30 Barbara Mintzes *et al.*, "Influence of direct to consumer pharmaceutical advertising and patients' requests on prescribing decisions: two site cross sectional survey" (2002) 324 *British Medical Journal* 278 at 278. Advertised products were defined in the study as drugs with the 50 highest advertising budgets in the US as well as drugs advertised to Canadian consumers in Canadian media reports from 1999 to 2000.
- 31 *Supra* note 22 at 1133.
- 32 Marco Bobbio *et al.*, "Completeness of reporting trial results: Effect on physicians' willingness to prescribe" (1994) 343 *Lancet* 1209 at 1209.
- 33 See e.g. Fredrik Brouneus, Anna Dahlin & Bjorn Beermann, "Press coverage and sales of Xenical in Sweden, 1998-2000" (2005) 61 *European Journal of Clinical Pharmacology* 285 at 285, where it is noted that positive media coverage before and during the launch of the medication "greatly increased public awareness of Xenical, thus promoting sales." Naturally, negative press can have the opposite effect. The negative press coverage of Norplant was so significant in the scientific and lay media that there is speculation it played a part in the decreased usage and eventual withdrawal of the medication from the market. See Entwistle, Watt & Johnson, *supra* note 23 at 1633.

