

CHILL WIND ON FREE SPEECH BLOWS IN FROM THE HILL

by

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Like the unfortunate Good Samaritan who personifies the adage that “no good deed goes unpunished,”¹ two medical societies have learned first hand that exercising their First Amendment right to speak on an issue of major public health importance may well exact its own toll from a Congress flexing its oversight and investigatory muscle.

On January 16, 2008, the U.S. House of Representatives Committee on Energy and Commerce and its Subcommittee on Oversight and Investigations (collectively, “the Committee”) sent a highly publicized letter commencing an inquiry into the circumstances surrounding the results from the so-called ENHANCE clinical trial comparing the combination cholesterol lowering drug Vytorin® with one of its constituents, simvastatin.² On January 15, 2008, the day after the release of the study results and the day before the Committee issued its letter commencing the investigation, the American Heart Association (“AHA”) and the American College of Cardiology (“ACC”) issued separate statements about the results from ENHANCE.³ In its statement, AHA:

- accurately reported the results of the study;
- said the study was “not large enough or long enough to determine whether the combination drug is more or less effective than the single drug in reducing heart attacks or deaths”;

¹See e.g. *In re Shawn P.*, 916 A. 2d 399, 406 n. 5 (Md. App. 2007) (“In assuming the role of Good Samaritan, [the Assistant Public Defender] has personified the adage, ‘No good deed goes unpunished.’”).

²See *Letter from Representatives John D. Dingell and Bart Stupak*, available at <http://energycommerce.house.gov/Investigations/DirectTo.shtml>.

³See Statement from the American Heart Association on ENHANCE study results, available at <http://www.americanheart.org/presenter.jhtml?identifier=3053094>; ACC Statement on ENHANCE Trial available at <http://www.acc.org/enhance.htm>.

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- suggested that larger studies be completed;
- identified high cholesterol as “a very important risk factor for cardiovascular disease”;
- stated that the combination drug “does not appear to be unsafe” and that there are circumstances where its use might still be appropriate and hence that it “does not believe that patients should stop taking the drug on their own”;
- identified statins as “the only drug class for lowering cholesterol that currently has evidence that heart attacks are prevented and life extended”; and
- based on all of this suggested that “patients on this combination drug should check with their doctor to see if they should stay on the drug, be switched to a statin alone, or take another combination of drugs for their cholesterol.”⁴

The ACC’s statement was similar.⁵

It is now reported that the Committee plans to send letters to the AHA and the ACC commencing an investigation into their respective relationships with the drug’s manufacturers because public statements about the ENHANCE study did not disclose the financial support they receive from them.⁶ Senator Charles E. Grassley, Ranking Member of the U.S. Senate Committee on Finance, has weighed in as well. In letters to the AHA and ACC,⁷ and while stating that he “does not disagree with the supportive tone” of their statements, Senator Grassley nevertheless asks, among other things, for the names of “all individuals involved in drafting” the statements and “all pertinent documents and communications, to include e-mails and drafts of the statement[s].” In other words, for speaking publicly about the ENHANCE study, and for doing little more than advising patients to speak with their doctors before unilaterally stopping Vytorin®, the AHA and ACC find themselves embroiled in a major congressional investigation.

Instead of encouraging the medical community to speak out on all sides of important public health issues, and thereby fostering robust discussion and debate, it appears as if the Committee and Senator Grassley are effectively chilling such speech by penalizing those organizations that have the temerity to engage in it through the *in terrorem* effect and cost of the investigation. While it is true of course that “an investigation [by Congress] is not a law, nevertheless an investigation is part of lawmaking” and is subject to the First Amendment.⁸ And even if, in a strictly legal sense, there is no technical First Amendment problem with the Committee’s

⁴*See id.*

⁵*See id.*

⁶*See* Stephanie Saul, *Heart Group Backs Drug Made By Ally*, N.Y. TIMES, Jan. 24, 2008, available at http://www.nytimes.com/2008/01/24/business/24heart.html?_r=1&pagewanted=print&oref=slogin.

⁷*Letter to M. Cass Wheeler, Chief Executive Officer, AHA* (Jan. 24, 2008), available at http://www.nytimes.com/2008/01/24/business/24heart.html?_r=1&pagewanted=print&oref=slogin; *Letter to James T. Dove, M.D., President, ACC* (Jan. 24, 2008), available at http://www.nytimes.com/2008/01/24/business/24heart.html?_r=1&pagewanted=print&oref=slogin.

⁸*Watkins v. U.S.*, 354 U.S. 178, 197 (1957).

investigation of the relationship between the medical associations and the pharmaceutical companies, “Abuses of the investigative process may imperceptibly lead to abridgment of protected freedoms. The mere summoning of a witness and compelling [them] to testify, against [their] will, about [their] . . . expressions . . . is a measure of governmental interference.”⁹

“Scientific and academic speech reside at the core of the First Amendment.”¹⁰ Indeed, no one can seriously question AHA’s and ACC’s status as scientific speakers engaged in the debate about some of the most significant public health issues of our time, even though they may receive some financial support from commercial interests.¹¹ Given the core First Amendment value of scientific speech by AHA and ACC about the ENHANCE study results, and their unquestionably sensible—benign—recommendation that patients speak with their doctors before precipitously stopping Vytarin®, the fact that they have become the objects of congressional investigations, and have even been asked to name names about the preparation of their respective statements, suggests that there is a chill wind on free speech blowing from Capitol Hill.

The investigations send a clear and powerful message to others about the consequences of speaking out on a matter of public concern, particularly when Congress perceives the speech to be in support of currently out-of-favor interests, such as pharmaceutical manufacturers. It will inevitably result in self-censorship and thereby “limit the supply of relevant information available to those . . . who seek to keep the public informed about important public issues.”¹² The mere threat of becoming embroiled in such investigations, and hence refusing to engage in the debate in the first instance, itself works a concrete constitutional injury.¹³ And unlike in *Nike v. Kasky*,¹⁴ where substantial First Amendment concern existed about imposing false advertising liability on account of a response by Nike on a matter of public concern—criticism of its labor practices abroad—AHA and ACC are third parties several steps removed from any underlying commercial interest that might justify the intrusion. “The interest in protecting such participants from the chilling effect of the prospect of expensive [investigation] is therefore . . . a matter of great

⁹*Id.*

¹⁰*Washington Legal Foundation v. Friedman*, 13 F. Supp. 2d 51, 62 (D.D.C. 1998), *appeal dismissed and judgment vacated in part by, Washington Legal Foundation v. Henney*, 202 F.3d 331 (D.C. Cir. 2000) (citing [Keyishian v. Board of Regents](#), 385 U.S. 589, 603 (1967); [Board of Trustees of Leland Stanford Junior University v. Sullivan](#), 773 F. Supp. 472, 474 (D.D.C. 1991) (“It is equally settled, however, though less commonly the subject of litigation, that the First Amendment protects scientific expression and debate just as it protects political and artistic expression.”)).

¹¹“The American Heart Association is a national voluntary health agency whose mission is: ‘Building healthier lives, free of cardiovascular diseases and stroke.’” Available at <http://www.americanheart.org/presenter.jhtml?identifier=10858>. “The mission of the American College of Cardiology is to advocate for quality cardiovascular care—through education, research promotion, development and application of standards and guidelines—and to influence health care policy.” Available at <http://www.acc.org/about/overview/overview.htm#intro>.

¹²*Nike, Inc. v. Kasky*, 539 U.S. 654, 683 (2003) (Opinion of Justice Breyer, joined by Justice O’Connor, dissenting from the Court’s decision concluding that, for jurisdictional reasons, the writ of certiorari was improvidently granted) (citations omitted).

¹³*Id.* at 667-668.

¹⁴539 U.S. 654 (2003) (dismissing writ of certiorari as improvidently granted).

importance.”¹⁵

In the Food and Drug Administration Amendments Act of 2007,¹⁶ Congress substantially expanded the requirements for public disclosure of clinical trial information. Presumably, one of the primary purposes for the new transparency requirements is to stimulate public discussion and debate about the merits of individual studies about a product and the study database as a whole. It seems somewhat ironic, then, that at the same time Congress is fostering open dialogue about the scientific evidence, it elects to penalize the AHA and the ACC for engaging in that very debate by subjecting their scientific utterances to the investigatory process. This would seem to work at direct cross-purposes with the underlying rationale for its own legislative mandate for greater transparency for clinical trial results, and more discussion and debate about them. At the end of the day, the message to the scientific community may well be to remain silent lest, like the Good Samaritan mentioned at the outset, you come to learn that “no good deed goes unpunished.”

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¹⁵*Id.* at 664 (Opinion of Justice Stevens, joined by Justice Ginsburg, and by Justice Souter, in part, concurring in decision to dismiss writ of certiorari as improvidently granted).

¹⁶Pub. L. No. 110-85, §801.