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A FEDERAL *UN*SALES FORCE?:

"ACADEMIC DETAILING" ON MEDICAL TREATMENTS AND THE OVERSIGHT IMPERATIVE

by
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Physicians and other health care professionals routinely receive visits from drug and medical device company representatives (commonly known as "detailers"), who pitch products on behalf of their company. Over the past three decades, a practice known as "academic detailing" (or "counter-detailing") has developed and been embraced by some health insurers and state governments to address rising health care costs. Independent academic detailers (typically clinicians, nurses, or pharmacists) meet with health care professionals and share information and educational tools about treatment options which are, according to the detailers' research, as effective as those advanced by company salespeople, and available at a lower cost.

The United States government is currently working to implement academic detailing on a national level. Congress allocated funds in a 2009 federal stimulus bill for such an effort and included further building blocks in the 2010 health care reform law. Programs which enhance medical professionals' knowledge should certainly be welcome by all who work in and benefit from America's health care system. Some questions have arisen, however, with regards to the government regulatory oversight of such academic detailing. Medical product industry detailers must comply with state and federal rules, as well as voluntary industry codes, with regards to their contact with physicians. At present, there is a great deal of uncertainty about the standards to which federally-funded academic detailers must conform, and whether there will be sufficient safeguards to ensure transparency, impartiality, and quality in the information and provider interactions.

Academic Detailing Evolution and Adoption. Dr. Jerry Avorn of Harvard Medical School is acknowledged as the godfather of academic detailing. In a 1983 *New England Journal of Medicine* article, "Improving Drug-therapy Decisions through Educational Outreach," he and Steven Soumerai described a randomized, controlled trial of clinical pharmacists visiting physicians' offices with the aim of reducing the excessive use of specific drug groups. The article relates that these visits led to a fourteen percent decrease in prescribing the drugs. The authors concluded that "academically-based 'detailing' may represent a useful and cost-effective way to improve the quality of drug-therapy decisions and reduce unnecessary expenditures."[1]

The concept of countering the drug and device salespeople's message was quite attractive to cost-conscious health insurers and state governments. Insurer Kaiser Permanente, for instance, has utilized

[1] N.E. J. OF MED., 1983; 308(24): 1457-63.

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academic detailing for over two decades.[2] Pennsylvania, Vermont, and South Carolina have created academic detailing programs. Pennsylvania's Independent Drug Information Service (IDIS), initiated in 2005, has been cited as a model and noted as a success by the Pew Prescription Project for generating cost savings from decreases in "inappropriate prescribing" that offset program expenses.[3] The state's Department of Aging has been paying a foundation at Harvard Medical School led by Dr. Avorn $1 million a year for three years to compile clinical research and disseminate that research through visits to physicians by trained academic detailers.[4] The IDIS detailers have focused their efforts on doctors who have at least 25 patients who receive state assistance to pay for their drug treatments, and who treat such ailments as chronic pain, hypertension, gastrointestinal symptoms, and high cholesterol.[5]

Emergence at the Federal Level. The federal government, until recently, has been largely uninvolved in the type of counter-detailing practiced by health insurers and states. Some Members of Congress became interested in such detailing early in the debate over health care reform. That interest first manifested itself in legislative form as an appropriation in the American Recovery and Reinvestment Act (ARRA). Congress included $1.1 billion for the Department of Health and Human Services (HHS) for the purpose of conducting "comparative effectiveness" research.[6]

At the urging of influential U.S. Senators and Representatives,[7] an entity within HHS, the Agency for Healthcare Quality and Research (AHRQ), is using its $300 million portion of the ARRA appropriation to lay the groundwork for a broader HHS-led academic detailing program. The Patient Protection and Affordable Care Act signed into law in March 2010 further solidified the importance of AHRQ in the scheme of disseminating government-funded comparative effectiveness research. The law created a non-profit entity, the Patient Centered Outcomes and Research Institute (PCORI), whose activities will be directed by a board of medical experts appointed by the head of the Government Accountability Office. AHRQ will be the primary outlet for PCORI's research and tools, and will be the recipient of twenty percent of PCORI's funding, which is expected to reach $500 million by 2015.[8]

In April 2010, AHRQ put out a solicitation for contractors to support an "Academic Detailing Initiative" with the overall goal of "contract[ing] with an organization to conduct activities related to Academic Detailing so that selected target audiences put AHRQ's comparative effectiveness products, tools, and research into practice."[9] On September 28, AHRQ awarded an $11.7 million, three-year contract to Total Therapeutic Management, a physician and patient education company, to integrate the agency's comparative effectiveness tools through on-site visits with clinicians, nurses, health plan formularies, and other professionals. AHRQ awarded four other contracts that day for the Academic Detailing Initiative: one for $18 million to Ogilvy Public Relations to create a publicity center, as well as another to the firm for $8.6 million to create regional dissemination centers; a $4 million continuing education award to Prime Education; and a $2.4 million contract to IMPAQ International "to evaluate the impact of the other four contracts."[10]

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[2]*See* Testimony of Ambrose Carrejo, Pharm.D., Special Committee on Aging, U.S. Senate, Mar. 12, 2008.

[3]*Academic Detailing: Evidence-Based Prescribing Information*, Apr. 2, 2009.

[4]Scott Hensley, *As Drug Bill Soars, Some Doctors Get an 'Unsales' Pitch*, WALL ST. J., Mar. 13, 2006.

[5]Kevin B. O'Reilly, *New reps, new rap: The counter-detailers*, American Medical News, Sept. 24, 2007.

[6]Such research has been defined as "the effort to manage medical technologies by evaluating their relative value." Peter J. Pitts, *'Comparative Effectiveness': Government's Way to Convert Patients Into Cost Centers?*, WLF LEGAL BACKGROUNDER, Feb. 13, 2009.

[7]Letter to Dr. Carolyn Clancy, Director, AHRQ, from Senator Herb Kohl and Representatives Henry A. Waxman and Frank Pallone, Sept. 15, 2009.

[8]John Wilkerson, *Contracts May Determine Whether Health Reform Pays Academic Detailers*, INSIDE CMS, Oct. 14, 2010, available at http://healthpolicynewsstand.com/Inside-CMS/Inside-CMS-10/14/2010/menu-id-316.html.

[9]Academic Detailing, Solicitation No. AHRQ-10-10011A (Apr. 28, 2010).

[10]Wilkerson, *supra* note 8.

Standards and Restrictions on Industry Detailing. Other than generalized references in the AHRQ contract solicitation that "Communication to these target audiences must be consistent with Food and Drug Administration (FDA) policies,"[11] no specific standards have been publicly announced to which federally-funded academic detailers must conform. This lies in stark contrast with the extensive state and federal controls placed on how pharmaceutical, medical device, and other health product businesses can conduct outreach and education.

The Federal Food, Drug, and Cosmetic Act, its amendments, and scores of Food & Drug Administration (FDA) regulations, guidance documents, and policies govern medical product companies' outreach and promotional efforts to health care providers and the public.[12] All promotional materials distributed by companies must undergo a rigorous FDA review process. Information must be accurate and fair regarding the products' risks and benefits. Omissions of material facts, including risk information in advertising and other promotional materials, can result in criminal sanctions. FDA closely monitors all communications between care providers and company representatives, including audio conferences, pamphlets handed out at professional meetings, mailings to physicians, and advertisements in medical journals. Federal regulators and prosecutors have focused especially strict enforcement on perceived promotion of "off-label" uses of drugs and devices, extracting billions of dollars in the settlement of such cases in recent years. Additionally, beginning in 2012, U.S. manufacturers of health care products will be subject to the Physician Payments Sunshine Act of 2009. The law requires companies to disclose gifts and payments made to physicians and teaching hospitals.

Numerous states and academic institutions have also adopted laws and rules which either prohibit or strictly control company gifts and payments to medical professionals. Massachusetts passed a law and implemented regulations to proscribe certain financial arrangements between companies and medical professionals, restrict meal purchases, and mandate that all company sales representatives receive state licensing and training.[13] Other states have adopted similar restrictions.[14] Pharmaceutical and medical device companies must also adhere to voluntary codes of conduct on interactions with medical professionals implemented and enforced by their respective trade associations.[15]

The Oversight Imperative for Academic Detailing. When the lack of specific oversight for government-funded academic detailers was noted by an industry spokesperson, Harvard Medical School's Dr. Avorn "defended his team's information as being above reproach" and retorted that such criticism was "ridiculous, offensive, self-serving, and ill-informed."[16] One can appreciate the passion with which Dr. Avorn supports counter-detailing. One should not, however, assume that educational activities and materials are inherently impartial, accurate, and balanced simply because they are being presented and funded by academics and government, rather than industry. Indeed, Dr. Avorn himself owns and operates a for-profit academic detailing company. There is an obvious business and financial interest in his ensuring that academic detailing is "above reproach."

Physicians and other medical professionals are certainly conscious of the cost of drugs and medical devices, but our primary duty is to provide each patient with the care best suited to them, individually. Tools such as comparative effectiveness research and academic detailing have been developed and applied in response to intense political and fiscal pressure to reduce health care costs. Academic detailing proponents such as Dr. Avorn, Senator Kohl, and the Pew Prescription Project all openly demonstrate the value of such programs by highlighting the drug costs savings they reportedly generate.[17] But with the federal government

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[11]Academic Detailing Solicitation, *supra* note 9, solicitation 1, May 17, 2010, Request for Proposal, at 11.

[12]Food, Drug & Cosmetic Act, Chapter V: Drugs and Devices.

[13]Pharmaceutical and Medical Device Manufacturer Conduct, 105 CMR 970.000.

[14]Vermont: S.48, 2009 Gen. Assem., Reg. Sess. (Vt. 2009); California: CAL. HEALTH & SAFETY CODE §§ 119400, 119402; Maine: MAINE REV. STAT.ANN. tit. 22, § 2698-A; Minnesota: MINN. STAT. §§ 151.461, 151.47; Nevada: NEV. REV. STAT. §639.570; West Virginia: W. VA. CODE § 5A-3C-13.

[15]Pharmaceuticals: *Code on Interactions with Health Care Professionals*.; Medical Devices: *AdvaMed Code of Ethics*.

[16]O'Reilley, *supra* note 5.

[17]Soumerai, *supra* note 1; Ltr to AHRQ, *supra* note 7; *Cost Effectiveness of Prescriber Education Programs*, Mar. 12, 2008.

itself as the nation's largest purchaser of medical products, and with the attendant impetus to reduce costs, what safeguards will be in place to ensure that academic detailers are not exceedingly influenced by those pressures? Will governmental academic detailers receive compensation in a pay-for-performance model, that is, bonuses based on how much they saved? Also, will specific doctors or those in certain practice areas be targeted based largely on those doctors' or the practice area's patterns of prescribing newer or more expensive treatments? Who will make those determinations and how?

As noted above, state and federal rules place controls on how industry detailers can encourage medical professionals to meet with them. Will such restrictions apply to academic detailers? Accounts of Pennsylvania's IDIS program report that counter-detailers offer free copies of Dr. Avorn's book, allow visited physicians to take a quiz and receive continuing-medical-education credits, and occasionally provide lunch.[18] Who will police their activities and investigate and prosecute flagrant disregard of the same rules that govern industry detailers? Also, will there be consequences if medical professionals choose not to meet with federally-funded detailers? Will such meetings be mandated for physicians who wish to care for patients receiving Medicare?

Further elaboration is needed on the general statement in the AHRQ solicitation that federal detailing contractors must comply with FDA policies. Must the studies and other materials academic detailers provide be peer reviewed and/or evaluated by federal health authorities? Must the materials offer clear and balanced risk and benefit information? What level of expertise and training must an academic detailer have? Studies by AHRQ and other federal entities such as PCORI will inevitably include consideration of off-label uses of drugs. Will academic detailers be permitted to disseminate facts about drug or device uses that do not appear on the FDA-approved label?

Policy-makers must address these issues to ensure that medical professionals, and in turn their patients, are confident in the accuracy and reliability of the academic detailing initiative and the information it disseminates. One possible model for developing clearer standards and oversight can be found in a bill introduced in 2009 by Senator Kohl, The Independent Drug Education and Outreach Act.[19] The bill, on which Congress never took action, specifically defines what types of entities are eligible to receive a federal detailing program grant; includes the quality of the educational materials among the criteria for contract award; and requires that the HHS director review and approve all educational materials, and that such materials be updated and reviewed again every two years. It also specifies that preference for federally-funded detailer visits be given to those medical professionals with a high percentage of Medicare and Medicaid patients. Finally, it requires HHS to promulgate regulations aimed at preventing conflicts of interest and ensuring the accuracy of the educational materials. Quite simply, the same rules that govern such activity for the pharmaceutical industry should be universally applied to government detailers.

[18]Hensley, *supra* note 4; O'Reilley, *supra* note 5.

[19]S. 767.