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Policies to Regulate Gifts to Physicians from Industry

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In 2000, pharmaceutical companies spent \$15.7 billion promoting their products, with the largest share (84%) directed toward medical professionals through commercial detailing, drug samples, and journal advertisements.[1] Studies suggest that pharmaceutical promotion influences professional judgment and prescribing behavior.[2] Most studies have focused on the effects of large gifts (eg, accepting money to attend or speak at educational symposia), but few well-controlled studies have assessed the long-term cumulative influence of small promotional items (eg, pens and other branded trinkets). There is still room for concern about such de minimis gifts, however, given the social science literature on gift exchange[3] and self-serving bias.[4]

These promotional efforts, if successful in unduly influencing professional judgment and prescribing behavior, may conflict with physicians' fiduciary responsibilities to their patients.[3] Concern with physician participation in unethical marketing arrangements has prompted episodic governmental interest in this area. In the early 1970s and 1990s, Congressional hearings were held to investigate pharmaceutical marketing practices. In addition, the Office of the Inspector General released several reports and a Fraud Alert on pharmaceutical promotion in the early 1990s and issued a voluntary Compliance Guidance for pharmaceutical companies in 2003.

In an attempt to forestall government intervention,[5] the American Medical Association (AMA) in 1990 adopted voluntary ethical guidelines on pharmaceutical gifts that were endorsed by the Pharmaceutical Manufacturers Association (now the Pharmaceutical Research and Manufacturers of America, PhRMA). Some observers perceived an abatement of marketing abuses, but it was short-lived. Within a few years, commercial detailers and physicians continued to exhibit behavior inconsistent with the guidelines.[5] In 2001, the AMA launched an educational campaign to promote the guidelines. PhRMA also adopted a new voluntary marketing code the following year.[6]

State legislative remedies for managing the boundaries between pharmaceutical promotion and education have gained popularity nationwide. In 2002–2003, state legislatures considered at least 30 bills related to pharmaceutical promotion.[7] These bills contained provisions that would, for example, eliminate pharmaceutical companies' tax deduction on marketing expenditures or prohibit certain gifts to physicians. Most of these bills have failed to pass, but on June 13, 2002, Vermont became the first state to require pharmaceutical companies to file annual reports disclosing gifts or payments to physicians exceeding \$25 in value.[7] An earlier version of the bill would have implemented pharmaceutical marketing licenses and required the reporting of all gifts.

Institutional policies have provided alternatives to legislation. Some residency programs have restricted commercial detailers' access to their trainees.[8] Proponents of restriction policies have encountered resistance,[9] while others have found their institutions threatened with the loss of pharmaceutical funding.[8] Few well-controlled studies have evaluated the long-term effects of restriction policies on actual behavior. Unintended consequences may result. For example, trainees in restricted-access programs may not learn how to interact ethically with commercial detailers, or pharmaceutical companies may pursue alternative marketing strategies that are less easily monitored.

Other institutions have employed pharmacists to supply unbiased, evidence-based prescribing information to physicians, a process known as "academic detailing" or "counterdetailing." [10] Similar teaching can be integrated into medical school curricula.[11] Randomized controlled trials conducted in five states confirm academic detailing to be cost-saving to the payer and effective in improving physician prescribing decisions.[10]

The recently enacted Vermont legislation includes a provision to implement counterdetailing.[7] However, no well-controlled studies have evaluated the effects of its gift reporting policy. The first report to be filed with the Vermont board of pharmacy will not be released until January 1, 2004, so it remains to be seen how this legislation will affect the behavior of both pharmaceutical companies and physicians.

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