



Paul J. Larsen
Assistant General Counsel
Deputy Compliance Officer

July 22, 2009

Office of Secretary of State
State of Colorado
1700 Broadway
Suite 250
Denver, CO 80290
Attn: William A. Hobbs

Re: Notice of Proposed Rulemaking; Office of Secretary of State; Campaign and Political Finance Rules; 8 CCR 1505-6 (May 29, 2009)

Dear Mr. Hobbs:

Please find enclosed comments of the Pharmaceutical Research and Manufacturers of America (PhRMA) regarding the above-referenced Proposed Rulemaking. PhRMA is a voluntary, non-profit association that represents the country's leading pharmaceutical research and biotechnology companies, which are devoted to inventing medicines that allow patients to live longer, healthier and more productive lives. Member companies are leading the way in the search for new cures. In 2008, PhRMA members invested approximately \$50.3 billion to develop new medicines.

If you have any questions regarding these comments, please feel free to contact me or Melanie Reed, Esq., Covington & Burling, (202) 662-5581 or mreed@cov.com.

Thank you for your consideration of these comments.

Best regards,

A handwritten signature in cursive script that reads 'Paul J. Larsen'.

Paul J. Larsen

Enclosure: PhRMA comments

Pharmaceutical Research and Manufacturers of America

950 F Street, N.W., Washington, D.C. 20004 • Tel: 202-835-3428 • Fax: 202-715-7030 • E-Mail: plarsen@phrma.org



Comments to the Colorado Secretary of State Regarding Campaign and Political Finance Rules

The Pharmaceutical Research and Manufacturers of America (PhRMA) represents the country's leading pharmaceutical research and biotechnology companies.

The Colorado Secretary of State, in a July 21, 2009 notice, requested comments on three questions related to whether the rulemaking should proceed, in light of the preliminary injunction issued by the District Court on July 17, 2009.¹ Recognizing that the Colorado Secretary of State may proceed with the rulemaking and with the creation of a list of sole source government contracts as required by section 16, PhRMA offers these comments.

PhRMA understands that the Colorado Secretary of State's Draft Proposed Rule 1.16.2 (Proposed Rule) would exempt certain contracts, including pharmaceutical rebate contracts (i.e., provider participation agreements) with Colorado, from the definition of a "sole source government contract," as that term is used in Article XXVII, Section 2(14.4) of the Colorado Constitution. PhRMA supports the Proposed Rule and urges the Colorado Secretary of State to finalize the exclusion of these agreements from the definition of sole source government contract.

Rebate and discount agreements between pharmaceutical companies and government bodies are structurally dissimilar from what would traditionally be considered sole source government contracts. These agreements do not involve discretionary spending decisions by state officials, but instead, set price discounts for payments by the state resulting from decisions made by individual doctors and their individual patients. In addition, these agreements often involve patented products in drug classes in which there are other patented products and the agreements are not generally awarded through a competitive bidding process where only one company's medicines can be prescribed. Furthermore, in the context of rebate agreements, the state itself does not make the decision to select and use, and is not the recipient of, any product.

In New Jersey, the state agency responsible for interpreting a similar set of restrictions on political contributions by state contractors also concluded that agreements between pharmaceutical companies and the government that provide for pricing discounts for the state's Medicaid program were not "contracts" in the sense intended by the law. New Jersey Public Law 2005, Chapter 51 (codified at N.J. Stat. Ann. §§ 19:44A-20.3) (New Jersey law bars companies that have agreements worth more than \$17,500 with the state, its purchasing agents or independent authorities to procure goods or services, from making certain political contributions to candidates for state office or current office holders). In implementing those restrictions, the State of New Jersey, Department of the Treasury, Division of Purchase and Property concluded that agreements with the Centers for Medicare and Medicaid Services (CMS) to provide rebates

¹ *Dallman et al. v. Ritter and Gonzales*, case #09cv1188 (consolidated with *Ritchie et al. v. Ritter and Gonzales*, case #09cv1200).

for drugs that are paid for by Medicaid were not “contract awards” covered by the state law regarding political contributions by state contractors. *See* State of New Jersey, Department of the Treasury, Division of Purchase and Property: *State Contractor Political Contributions Compliance, Chapter 51 Q & A*, Question 109.²

Similarly, the Department of Treasury concluded that Medicaid rebate agreements were not “contracts” as defined in New Jersey’s law. Using a series of questions and answers as a form for its advice, the Department of Treasury, Division of Purchase and Property’s Question 110 asked:

The State has a similar form agreement to the Medicaid rebate agreement concerning the [Pharmaceutical Assistance to the Aged and Disabled] PAAD and Senior Gold programs. Signature of the New Jersey drug rebate agreement is mandated in order for the drugs produced by a manufacturer to be eligible for State funding when dispensed to PAAD or Senior Gold beneficiaries. The provision of drugs in these two programs are not subject to the public bidding provisions. Is it correct to assume that the pharmaceutical manufacturers that enter into rebate agreements with the Department of Health and Senior Services are not prohibited from making political contributions under E.O. 134 (Chapter 51)?

Answer: The State rebate agreements under the referenced programs do not constitute contract awards, and therefore (1) are not subject to Chapter 51 (EO 134), and (2) do not trigger the restrictions of Chapter 51.

Id.

That conclusion is equally warranted here. While provider participation agreements can take several forms, most frequently the contracts between pharmaceutical companies and a state provide no more than a discounted pricing structure, which is available to the state for as long as the state makes the manufacturer’s drug available without disadvantaging it vis-à-vis other drugs in the same therapeutic class. Unlike a traditional contract, these agreements do not guarantee the pharmaceutical company that any particular amount of products will be selected by physicians and patients and therefore sold by the manufacturer, they do not preclude the state from reaching similar agreements with other pharmaceutical companies providing other products in the same drug class or to treat the same disease or condition, and the state is not the actual decision-maker about whether to use the manufacturer’s products. Instead, individual physicians and their patients decide whether to use the products and if so, in what quantity. Thus, the rebate contracts do not serve as a contract for the sale of goods but rather as

² <http://www.state.nj.us/treasury/purchase/execorder134Q&A.htm> (last viewed on July 20, 2009).

an agreement on an amount of a rebate that will be paid to the state for products that program beneficiaries and their physicians have chosen to use.

Pharmaceutical companies also often enter into discount contracts that allow state-supported healthcare facilities to pay for medicines at a negotiated price or rebate amount. Under these types of agreements, which are also not generally competitively bid, the state obtains a right to pay a discounted price in exchange for not restricting access to agreed-upon drugs. Similar to rebate agreements, discount contracts also merely establish a pricing structure and leave the decision over what, if any, products will be purchased to the discretion of the individual treating physician.

Rebate and discount agreements help ensure that important therapies are available at an affordable rate to beneficiaries of Colorado's health care services while leaving decisions over the demand for a pharmaceutical company's drugs in the hands of physicians and beneficiaries and not state officials. For this reason, PhRMA believes that these forms of agreements are appropriately excluded from the definition of a sole source government contract, and PhRMA urges the Secretary of State to finalize the exclusion of these agreements from the definition of sole source government contract.

For these reasons, PhRMA supports the Colorado Secretary of State's Proposed Rule.