Statement PhRMA

Vermont Hearing on Advisability of Requiring Disclosure of
Free Samples of Prescribed Products Given to
Vermont Health Care Providers

PhRMA Statement
October 27, 2009

The Pharmaceutical Research and Manufacturers of America (PhRMA) is a voluntary, non-profit organization representing the country's leading pharmaceutical research and biotechnology companies. In 2008, PhRMA members invested approximately $50.3 billion to develop new medicines to allow patients to live longer, healthier, and more productive lives. PhRMA is pleased to provide the following information to the Attorney General and the Commission on Health Care Reform.

The Place of Prescription Drugs within Healthcare

While prescription drugs, both pharmaceuticals and biologics, are an important part of any healthcare system, they account for only 10% of all healthcare expenditures. Within that 10%, a growing number of prescriptions are filled with generic rather than brand drugs. Nationwide, 72% of all prescriptions are filled with generic drugs, and in Vermont that figure is estimated to be higher than 70 %. In 2009, the journal, Health Affairs, reported that the Vermont generic use rate in Medicaid increased 5.6 % from 2005 to 2006. Vermont has a mandatory generic substitution law, so patients receive a generic drug when one is available. Thus, only a small number of patients actually are taking brand name medicines, usually because they have been unsuccessful on an available generic medicine for their disease or condition, or because no generic medicines are available.

The increasing use of generic medicines highlights one of the important roles for prescription drug samples—to help patients and physicians determine whether a brand medicine, often a relatively new medicine, will work for the patient before the patient or the patient's insurer invests in the cost of a full prescription. The final determination about what medicine the patient takes for the long term is controlled by the formulary imposed by the patient's insurer, including the Medicaid preferred drug list and the prior authorization system. The volume of generic drugs dispensed affirms that formularies and generic substitution are the major forces in determining whether a patient receives a newer brand medicine or an older generic medicine.

As part of the review of drug samples and the question of whether the state should require manufacturers to report to the state on the distribution of samples, it will be helpful to understand the extensive regulation of samples that already exists. The state should consider carefully whether there would be any benefit to the state of Vermont to create an additional state system to add new and different reporting requirements in light of the existing system for

regulation of the distribution of samples.

The Purpose of Prescription Drug Samples

A drug sample is provided to a healthcare provider to "test" the drug, but not for sale. Samples make physicians aware of the availability of a new drug and provide the prescriber the opportunity to determine if the new drug product is appropriate for patients by means of a short trial period, at no cost to the patients. The availability of drug samples also helps ensure that there is no delay in initiation of therapy, an obvious benefit to the patient.

Drug samples are closely regulated by the FDA in accordance with federal law enacted in 1987, to ensure that drugs purchased or received by consumers are safe and effective. The extensive regulation was intended to eliminate any risk that drug samples would be adulterated, misbranded, or expired. Each of these terms has a special meaning under the Food, Drug, and Cosmetic Act, the statute that regulates the approval, manufacture, and sale of prescription drugs.

> Congressman John Dingell, then Chairman of the House Energy & Commerce Committee, highlighted that the "distribution of drug samples to patients . . . is a useful medical tool because the use of samples enables doctors to more quickly identify the appropriate drug therapy for a patient at less cost." 133 Cong. Rec. 3023-24 (1987). He added that "the availability of samples can be beneficial in acute care situations and in circumstances where access to a pharmacy is difficult because of distance, time of day, or lack of transportation." *Id.*

Congressman Dingell identified the key uses of prescription drug samples, to allow physicians and patients to determine whether a new drug is effective for the particular patient, and to allow the patient to begin therapy immediately, without the delay of getting to the pharmacy and waiting for the prescription to be filled and without the expense of purchasing an entire 30 or 90 day prescription. Drug samples are particularly useful when physicians must adjust the dose of a medicine to obtain the best result for each unique patient, so the patient may need to change doses one or more times before completing any 30-day prescription. For new medicines, samples also allow the physician to work with patients to learn how they respond to the medicine and to assess compliance issues. This may be especially important for medicines with new or unique methods of administration.

Many physicians report that the opportunity to provide patients with a drug sample of the medicine for the patient to see whether it works and to evaluate whether the side effects are acceptable, enhances the patient's willingness to comply with the physician's recommended treatment plan and improves the patient's trust in the physician. Compliance with the physician's prescribed treatment, whether it is a change in behavior, a prescription medicine, or both, is particularly important for patients with chronic conditions, which accounts for 75 percent of all healthcare spending.

Physicians also report that, in many instances, they provide drug samples to patients who have no insurance or no drug coverage or are otherwise having financial difficulties. Note that pharmaceutical manufacturers, including all PhRMA members, have patient assistance

programs for patients who are unable to afford their medicine. PhRMA works with many others to operate the Partnership for Prescription Assistance to help patients gain access to those programs. Pharmaceutical companies recognize that physicians may provide samples to such patients to ensure patients have access to the right medicine as quickly as possible, especially while waiting for the medicine to arrive from the manufacturer's patient assistance program. In addition, some physicians provide samples to patients who are in the Medicare coverage gap.

FDA Regulation of Prescription Drug Samples

FDA has long-established regulations that cover all aspects of the packaging, distribution and accounting for prescription drug samples. Only the manufacturer and an authorized distributor may distribute drug samples, and they may be distributed only to a healthcare provider who is licensed to prescribe in the state where the provider's practice is located.

A provider must request samples, and the request must include the practitioner's address; state license number; the drug, the drug's manufacturer and the quantity of samples requested; the date of the request; and the practitioner's signature. Once the manufacturer or authorized distributor has received the request, the samples may be delivered by mail, a common carrier, or a pharmaceutical representative. Regardless of the method of delivery, the manufacturer must receive a signed receipt from the prescriber. The manufacturer must keep both the request and the receipt for 3 years.

There are provisions for the licensed healthcare provider who receives drug samples to in turn donate those samples to a charitable institution, and there are detailed rules about the obligations of the charitable institution to maintain the quality, integrity and effectiveness of the samples and to maintain records of such donations and all samples in stock.

Manufacturers must label all drugs samples as "sample" or "not for sale," so that everyone within the system is aware that the package contains a sample that can not be sold or billed to a payer. In addition, the sample package must contain a lot control number to allow the manufacturer to trace the sample to the licensed provider to whom it was delivered. This is important for product recall purposes, as well as for enforcement of the "not for sale" provision.

Manufacturers must store and handle drug samples under conditions that maintain the stability, integrity, and effectiveness of the medicine. Manufacturers must conduct an annual physical inventory of all drug samples, and reconcile the results with the most recent prior inventory. In addition, manufacturers must conduct audits of pharmaceutical representatives handling samples.

If a manufacturer believes that anyone is diverting drug samples or falsifying any records related to the distribution of drug samples, the manufacturer must report the suspicion to the FDA within 5 days, conduct an investigation, and report the results to the FDA. Likewise, the manufacturer must report any significant loss or known theft of samples, conduct an

investigation, and report the results to the FDA.

The manufacturer must have written policies and procedures to complete all the record-keeping, investigation, and reporting obligations.

The FDA has authority to impose penalties on manufacturers for violations of the regulations governing the distribution of drug samples. In addition, when a pharmaceutical representative who is found guilty of violating the prohibition on the sale, purchase or trade of a drug sample, the manufacturer that employed that representative must notify the FDA within 30 days of the conviction, or face a penalty for failure to notify the FDA. There have been public reports of prosecutions of physicians charging payers for administering samples to patients.

Both pharmaceutical representatives and healthcare providers face possible prison sentence of up to 10 years, and a civil penalty of $250,000, or both, for knowingly selling, purchasing, or trading a prescription drug sample or offering to do so.

Additional detail about the FDA's regulations for prescription drug samples can be found in the attached memorandum from Covington & Burling.

State Regulation of Prescription Drug Samples

Vermont requires manufacturers that want to distribute prescription drug samples in the state to obtain a wholesaler's license from the Board of Pharmacy. Vt. Stat. Ann. tit. 26, § 2061(b); Bd. of Pharmacy Adm. Rules § 17.1–.4. Wholesale distribution means "the distribution of prescription drugs to persons other than a consumer patient," Vt. Stat. Ann. tit. 26, § 2022(17), and is interpreted by the Board of Pharmacy to include the distribution of prescription drug samples by manufacturers and their authorized distributors.

Manufacturers that want to distribute controlled substances, referenced in the Vermont statutes as "regulated" drugs, must register with the federal Drug Enforcement Administration as well as the license from the Vermont Board of Pharmacy. Vt. Stat. Ann. tit. 26, § 2061(b); Bd. of Pharmacy. Adm. Rules § 17.25. If the manufacturer wants the pharmaceutical representative to distribute the drug, the manufacturer must comply with three requirements: (1) ensure there is no charge for the sample, either direct or indirect; (2) limit the distribution to no more than "ten times the manufacturer's recommended maximum individual dose"; and (3) mark each individual tablet or capsule with either the words "sample" or "not for sale." Vt. Stat. Ann. tit. 18 § 4213(a)(2).

The Vermont Board of Pharmacy regulations require that manufacturers maintain an inventory of prescription drugs, Bd. of Pharmacy Adm. Rules § 17.16, 20. The manufacturer must report any theft. In addition, manufacturers must report within 48 hours to the Vermont Board of Pharmacy any "disasters, thefts, accidents and emergencies" that may affect the strength, purity, or labeling of their drugs. Vt. Stat. Ann. tit. 26, § 2063(b).

The legislature exempted the reporting of samples intended for patient use from the expanded reporting requirement and directed the Attorney General, working with the Commission on Health Care Reform, to study whether information about "the provision of samples to health care providers by manufacturers of prescribed products" should be included in future reporting requirements that the legislature might impose on pharmaceutical, biological, and device manufacturers. Section 5a of S 48. The Attorney General's office is directed to report its findings to the relevant legislative committees by December 15, 2009. However, the Attorney General's office, without regard to the intent of the legislature in Sec 5a. of the statute, has stated in guidance that samples of biologics and devices must be disclosed in the 2010 report.

In addition to altering the clear intent of the legislature when it required a study of the provision of samples of "prescribed products," the Attorney General's actions evidence confusion about pharmaceutical and biologic products. While the U.S. Food and Drug Administration (FDA) approves medicines under two different regimes, one for pharmaceuticals and one for biologics, in many instances, similar products are approved under each of the regulatory systems. Many new medicines, where physicians and patients may need to use a drug sample to determine whether the product is effective, are approved as biologics and thus would be immediately subject to the reporting requirements.

This decision was made, without any public notice or comment, and was "announced" through the process of posting additional questions and answers on the Attorney General's website. This action does not seem consistent with the legislature's interest in transparency as part of healthcare. PhRMA strongly urges the Attorney General to revise this policy.

Response to Questions Posed for the Hearing

1. How are free samples distributed to Vermont prescribers now?
   Drug samples may be provided by pharmaceutical representatives during an office visit and by mail or common carrier. Samples may be provided only on the written request of the prescriber, with detailed information about the prescriber and the pharmaceutical or biologic for which a sample is requested, as required by federal law.

2. What records do manufacturers keep of the distribution of free samples?
   Manufacturers must keep detailed records of all aspects of sample distribution, as required by federal law, and must report to FDA and to state if significant samples are missing

3. What is the approximate volume and value of free samples being distributed in Vermont?
   PhRMA has no information about volume of free drug samples distributed in Vermont. PhRMA was not able to find any credible source of information about volume of samples distributed within any region or throughout the country.

- The value of pharmaceutical and biologic samples distributed is zero. A sample has no value to the physician. Samples are intended for patient use, marked as "sample," "not

for sale." Each pharmaceutical company that distributes samples must train representatives and anyone else involved in sample distribution that it is a violation of federal law to sell, offer for sale, or bill any payer for providing, dispensing or administering sample. Pharmaceutical representatives providing samples must convey to the physician that samples can not be sold or offered for sale and the healthcare provider can not charge a payer for a sample provided to a patient.

4. Would disclosure of the distribution of free samples have a significant impact on the willingness of providers to accept those samples?
PhRMA does not maintain comprehensive information about the effect on healthcare providers and disclosure of samples. Comments from providers and clinics serving low income and uninsured patients mention that disclosure would discourage accepting samples for a number of reasons.

- One important reason is the risk that public reports would describe drug samples as "gifts" to the receiving physician. Physicians recognize that samples are not "gifts," but are intended to benefit patients.

- Public listing that a clinic has a number of drug samples of particular products would put the clinic at risk of break-ins by people seeking the listed drugs, or presuming that if the clinic has the listed drugs, the clinic may also have other drugs potentially subject to abuse.

- It's not clear what the value would be of disclosing information about drug samples. The public is aware that pharmaceutical companies provide samples of many medicines.

- In addition, the process of collecting and reporting information about samples could be quite complicated. While manufacturers record the name of the requesting and receiving prescriber, in clinics and some group practices, the samples may then be given to patients by more than one prescriber. While the clinic or group practice maintains a record of what patients were given what samples, the manufacturer would have no way of tracing the specific sample to a specific prescriber within the clinic.

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Recommendations

In conclusion, PhRMA recommends:

- Support the availability of drug samples as trial courses of therapy to determine tolerability and effectiveness for an individual patient prior to filling an entire prescription.

- Disclosure/reporting of drug samples should not be a part of physician marketing disclosure requirements. Samples provide no economic benefit to the physician, but do provide direct benefit to the patients who are provided immediate access to their medicine.
- Mandated disclosure/reporting requirements may inappropriately characterize or suggest that samples are a gift to physicians and/or provide an economic benefit to that physician. This inaccurate characterization or suggestion may deter a physician from sampling to the detriment of patient health.
- Drug samples provide direct benefit to the patient and PhRMA opposes any reporting requirements that may result in intended or unintended restrictions that would inhibit that patient benefit.

Attachment

Memorandum from Covington & Burling, "Federal and Vermont Regulation of Drug Samples"