



**Irrational Medicine: Limitations on Medicare Drug Coverage for Kidney
Patients Costs Taxpayers Millions of Dollars**

Prepared for Rep. Tammy Baldwin

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EXECUTIVE SUMMARY

At the request of Rep. Tammy Baldwin of Wisconsin, the minority staff of the Committee on Government Reform investigated the use of prescription drugs by patients suffering from kidney disease. The investigation found that the legislative prohibition preventing the Medicare program from covering self-administered prescription drugs for patients undergoing kidney dialysis may be costing the federal taxpayer well over \$100 million each year. The investigation found that the legislative prohibition also forces kidney dialysis patients to incur tens of millions of dollars in avoidable medical expenses each year.

Current federal policy requires Medicare to treat drugs with the same therapeutic benefits in fundamentally different ways. For drugs injected into a patient by a physician, Medicare is allowed to pay most of the cost of the drug. But if the drug is taken orally by the patient, Medicare is prohibited from paying for the drug, even if the oral version of the drug is equally safe and effective and less expensive. In the case of patients suffering from kidney disease, this arbitrary legislative distinction produces costly results.

Virtually all kidney patients suffer from some degree of bone disease, stemming from a lack of vitamin D, high blood phosphorous, and low blood calcium levels. Renal bone disease can be treated with a vitamin D hormone that is available in both injectable and oral versions. Because Medicare pays most of the cost of injectable drugs, the vast majority of patients who undergo hemodialysis and suffer from calcium deficiencies take one of two injectable drugs, Calcijex and Zemplar, to prevent and treat bone disease. Only a small percentage of hemodialysis patients take one of the two oral drugs, Hectorol and Rocaltrol, to prevent and treat bone disease. The oral drugs have been found to be as safe and as effective as the injectable drugs, yet the oral drugs are only a fraction of the cost of the injectable drugs.

As a result of Medicare's inability to pay for the two oral drugs, the federal government wastes millions of dollars each year. In 2000, it is estimated that Medicare will pay approximately \$167 million for vitamin D hormone injections for hemodialysis patients. If these patients were to use the oral drug Hectorol instead of one of the injectable drugs, the Medicare program could save as much as \$122 million.

The federal policy that prohibits Medicare from paying for Hectorol is also costly to the patients undergoing hemodialysis. The Medicare program pays for only 80% of the costs of vitamin D hormones, requiring patients to pay the remaining 20%. In total, this copayment requirement forces patients to pay approximately \$44 million per year for vitamin D hormone treatments. If Hectorol were eligible for Medicare reimbursement, these patients could reduce their annual drug expenditures by as much as \$35 million per year.

The principal beneficiary of the current system of federal reimbursement for hemodialysis drugs is Abbott Laboratories, the company that makes Calcijex and Zemplar. One of the drug manufacturers most penalized by the current system is Bone Care International, the company that makes Hectorol.

I. BACKGROUND ON END-STAGE RENAL DISEASE

An estimated 370,000 Americans suffer from kidney failure, more formally known as end-stage renal disease (ESRD).¹ Common causes of ESRD are diabetes (33%), high blood pressure (24%), and kidney inflammation (17%). ESRD affects both men and women and persons of all races, although African Americans and Native Americans are affected in disproportionate numbers.² The mean age of ESRD patients is 61 years old.

Kidney failure prevents the kidneys from excreting toxic substances such as urea and creatinine from the body. When these substances accumulate to high enough levels, patients will exhibit tiredness, weakness, loss of appetite, and vomiting. If left untreated or if treated inadequately, kidney failure will ultimately lead to death. More than 50,000 Americans die each year as a result of kidney diseases.

II. TREATMENT OF END-STAGE RENAL DISEASE

ESRD is primarily treated in three different ways: kidney transplantation; hemodialysis; and peritoneal dialysis. As a result of improvements in the treatment of ESRD and coverage of ESRD patients under Medicare, there are now over 300,000 ESRD patients alive in the U.S., compared to only 11,000 living patients in 1973.

For many patients, the most desirable treatment is the receipt of a transplanted kidney. However, only about 11,000 patients receive transplants each year because of a shortage of suitable organ donors. As a result, only 28% of ESRD patients are surviving recipients of kidney transplants. For all other patients, dialysis is the only way to alleviate the effects of kidney disease. Dialysis does not cure the underlying disease.

Hemodialysis is the most common form of dialysis and is used by 63% of all ESRD patients. During hemodialysis, the patient's blood travels through tubes into a dialysis machine. Inside the machine, excess waste products, salt, and water are filtered out, and the cleansed blood is returned to the patient's body through another set of tubes. Hemodialysis patients undergo three treatments a

¹This figure is derived from data indicating that there were 304,000 ESRD patients in 1997. U.S. Renal Data System, 1999 Annual Report, Chap. 2 (hereinafter "1999 USRDS Report") (located at <http://www.usrds.org/chapters/adr.html>). According to Professor Stephen W. Schondelmeyer, the number of ESRD patients is increasing by 7% each year. Stephen W. Schondelmeyer & Enrique Seoane-Vazquez, *Medicare & the Vitamin D Analog Market* (Mar. 15, 1999). Based on this rate of increase, the number of ESRDS patients in 2000 is estimated to be 370,000.

²African Americans comprise approximately 32% of ESRD patients but only 12 percent of the U.S. population. Native Americans comprise 1.5% of ESRD patients but only 0.8 percent of the U.S. population.

week, usually at a dialysis center, under the supervision of a nurse or clinician.³

The loss of kidney function can often lead to dangerously low blood calcium levels for ESRD patients. When functioning properly, the kidneys help maintain the proper level of calcium, phosphorous, and vitamin D in the blood. Advanced renal failure prevents the kidneys from excreting phosphorous, causing the phosphorous levels in the blood to rise. To maintain the balance between phosphorous and calcium, the body releases parathyroid hormone to signal the bones to release calcium into the blood. If left untreated, this process can lead to severe bone loss. Patients suffering from this condition are treated with a vitamin D hormone often referred to as calcitriol. Vitamin D hormone regulates parathyroid hormone and enhances the body's ability to absorb and use calcium and thus can reverse the process that causes bone breakdown.

According to one survey of ESRD patients, 42% of new hemodialysis patients take some form of vitamin D hormone.⁴ Interviews of physicians and nurses experienced in treating ESRD patients suggest that the actual percentage of patients taking a vitamin D hormone may be as high as 60% to 70% of all hemodialysis patients.⁵

Vitamin D hormones are available in both injectable and oral versions. The most widely prescribed injectable version, Calcijex, is delivered intravenously to the patient during hemodialysis, usually three times a week. There are two oral versions, Hectorol and Rocaltrol, which are taken daily in capsule or oral solution form.⁶

The oral and injectable versions of vitamin D hormones contain similar active ingredients and

³Approximately 9% of ESRD patients are treated with peritoneal dialysis, which uses the lining of the abdomen to filter the blood. In peritoneal dialysis, a solution is introduced into the peritoneal cavity through a catheter. Excess waste products and water pass through the membrane lining of the peritoneal cavity into the dialysis solution, which is drained out of the abdomen and discarded. Peritoneal dialysis is performed by the patient several times each day.

⁴U.S. Renal Data System, 1998 Annual Date Report, Chap. 4 (hereinafter "1998 USRDS Report") (located at <http://www.med.umich.edu/usrds/download/download.html>).

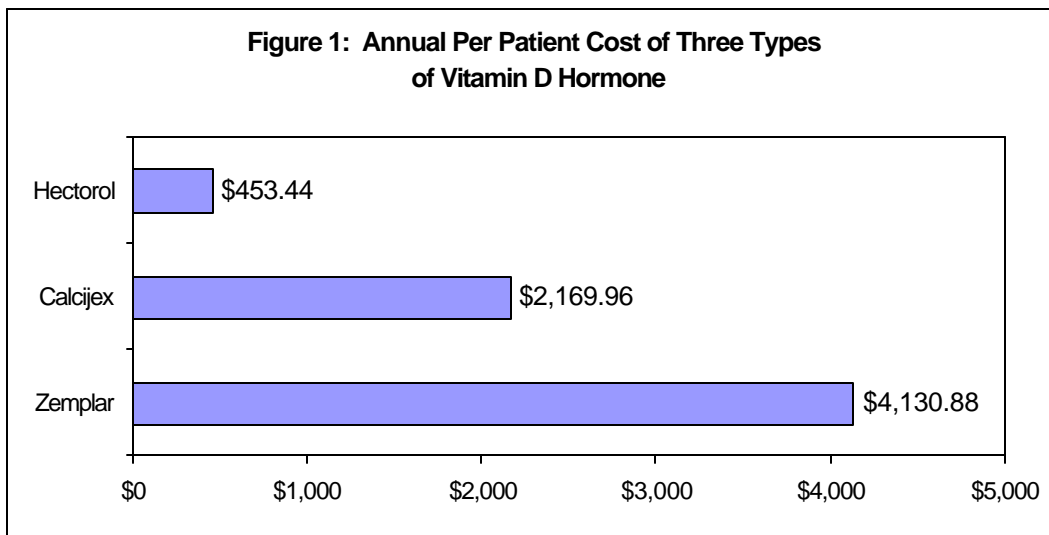
⁵Schondelmeyer, *Medicare & the Vitamin D Analog Market*, *supra* note 1.

⁶The cost benefits of Rocaltrol, which is manufactured by Hoffman-La Roche, were analyzed in a previous study by the Government Reform Committee minority staff. That study concluded that Medicare coverage of Rocaltrol could also save the federal government and ESRD patients significant sums. See House Committee on Government Reform, *Irrational Medicine: Limitations on Medicare Drug Coverage for Kidney Patients Costs Taxpayers Millions of Dollar* (Report for Rep. Rush D. Holt) (Jan. 10, 2000).

have similar therapeutic effects on ESRD patients. In a 1996 article in *Pediatric Nephrology*, two researchers at Duke University Medical Center reviewed the results of six different clinical studies of calcitriol usage and found that there were no differences in either efficacy or safety between the injectable and oral versions.⁷ They reported that “the overall effectiveness of calcitriol therapy . . . is not dependent on the route of administration.” The researchers concluded that whether oral or injectable vitamin D hormones are used “is largely a matter of convenience, compliance, and cost rather than one of therapeutic advantage.”⁸

Despite the fact that Calcijex and Hectorol are similar in terms of efficacy and safety, the prices of the two drugs are quite different. This study estimates that the annual per patient cost of Calcijex is \$2,169.96. In contrast, the annual per patient cost of Hectorol is only \$453.44, 79% less than the cost of Calcijex.⁹

Until recently, Calcijex was the only injectable form of vitamin D hormone. In April 1998, Abbott Laboratories, the manufacturer of Calcijex, received approval from the Food and Drug Administration to manufacture Zemplar, a new injectable form of calcitriol. This study estimates that the annual cost of Zemplar per patient is \$4,130.88, almost double the cost of Calcijex and more than nine times the cost of Hectorol (see Figure 1).



⁷L. Darryl Quarles and Olafur S. Indridason, *Calcitriol Administration in End-Stage Renal Disease: Intravenous or Oral?* *Pediatric Nephrology*, vol. 10, 331-36 (1996).

⁸*Id.* at 333, 335.

⁹The annual per patient costs of the three vitamin D hormones were determined using the lowest recommended maintenance drug dosages and the average wholesale prices of the drugs. For more detail, see the appendix accompanying this report.

III. LIMITATIONS ON MEDICARE COVERAGE OF VITAMIN D HORMONE

A. General Reimbursement Limitations

Since 1965, the federally funded Medicare program has provided medical benefits to persons over age 65 and to disabled persons under age 65. In 1972, Congress included persons suffering from kidney disease, regardless of age, within the class of disabled persons eligible for Medicare coverage. Medicare covers the cost of kidney dialysis, hospital stays, organ transplantation, physician services, and other associated medical treatments. In 1997, the most recent year for which data is available, Medicare spent \$10.8 billion to treat ESRD patients.¹⁰

Like the elderly patients who receive the bulk of Medicare services, ESRD patients are not covered for the cost of most prescription drugs. With a few limited exceptions, federal law only covers “drugs and biologicals which cannot . . . be self-administered.”¹¹ Under this policy, drugs injected into a patient by a doctor or nurse are covered by Medicare, while those taken orally by a patient are not.

For those drugs covered by Medicare, only a portion of the drug’s cost is actually reimbursed. Medicare Part B, which covers medical treatment other than hospital care, requires the patient (or his insurer) to make a 20% copayment for any services provided under Medicare Part B, including physician-administered drugs.¹²

B. Reimbursement Limitations for Vitamin D Hormone

The general prohibition against Medicare coverage for “self-administered” drugs creates an arbitrary distinction between therapeutically equivalent renal drugs. Because Calcijex and Zemplar, the injectable versions of vitamin D hormone, are administered by a nurse or dialysis clinician during hemodialysis, the costs of the drug are covered by Medicare. In contrast, a similar oral version, Hectorol, is self-administered by the patient and is not covered by Medicare, even though Hectorol has similar therapeutic effects as Calcijex and Zemplar and is less expensive.¹³

¹⁰1999 USRDS Report, Chap. 10.

¹¹42 U.S.C. § 1395x(s)(2)(A) & (B).

¹²42 CFR § 410.152(b).

¹³Medicare’s arbitrary treatment of vitamin D hormones differs from Medicare’s treatment of certain other oral drugs. For anti-cancer drugs, oral versions are covered if they contain the same active ingredient as another version of the drug that would otherwise be covered by Medicare. 42 U.S.C. § 1395x(s)(2)(Q). For anti-vomiting drugs used in chemotherapy, oral versions are covered if they are intended “as a full replacement for the anti-emetic therapy which would otherwise be

Because of the federal policy allowing Medicare coverage of Calcijex and Zemplar but not similar oral versions, the vast majority of ESRD patients using a vitamin D hormone take the injectable drugs. The best data on the percentage of hemodialysis patients taking injectable vitamin D hormones, as opposed to oral versions, is from the U.S. Renal Data System survey of 20,000 randomly selected ESRD patients between 1995 and 1997. This survey found that 81% of hemodialysis patients who took a vitamin D hormone were prescribed an injectable version, as opposed to 19% who were prescribed an oral version.¹⁴

It is difficult to ascertain precisely the extent of Calcijex and Zemplar usage among ESRD patients. However, it is estimated that Medicare will spend \$167 million on reimbursements for injectable vitamin D hormones in 2000.¹⁵ Based on this estimate, it appears that as many as 101,000 ESRD patients may be taking an injectable vitamin D hormone.¹⁶

IV. THE COST TO THE FEDERAL GOVERNMENT

The current policy of covering only the expensive, injectable version of vitamin D hormone, but not the less expensive, oral version, wastes federal taxpayer dollars.

If Medicare covered Hectorol as well as Calcijex and Zemplar, Medicare reimbursements would be reduced substantially. On a per-patient basis, one year's supply of Calcijex costs \$2,169.96. In contrast, on a per-patient basis, one year's supply of Hectorol costs only \$453.44, or 79% less than Calcijex. These per-patient savings can be extrapolated to provide an estimate of potential nationwide savings. If all ESRD patients currently taking Calcijex switched to Hectorol, Medicare would reduce its expenditures on vitamin D hormones by 79%. Such a reduction in expenditures would save American taxpayers \$132 million.

According to the 1998 USRDS survey, a small percentage of ESRD patients -- 19% of hemodialysis patients and 79% of peritoneal dialysis patients -- currently use an oral form of vitamin D hormone. If the Medicare program were authorized to provide reimbursement for Hectorol, these patients would then become eligible for reimbursements. Extrapolating from the USRDS survey data, it

administered intravenously.” 42 U.S.C. § 1395x(s)(2)(T).

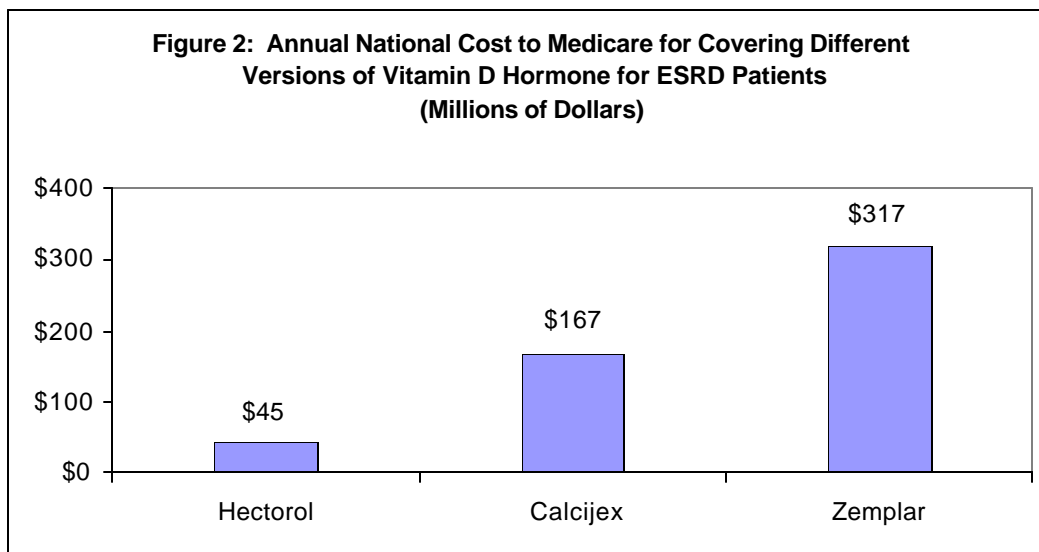
¹⁴1998 USRDS Report, Chap. 4.

¹⁵HCFA has estimated that Medicare made \$145.5 million in reimbursements for injectable vitamin D hormones in 1998. The \$167 million estimate in this study is based on Schondelmeyer's assumption that the number of ESRD patients is increasing at a 7% annual rate.

¹⁶This figure is derived by dividing \$167 million (the annual amount of Medicare reimbursements) by \$1,649.17 (the annual cost to Medicare for a patient using Calcijex).

is estimated that approximately 30,000 ESRD patients currently use an oral version. Covering these patients would cost Medicare approximately \$10.3 million each year. Adjusting for this increased cost, the total potential savings to the taxpayer from a change in current Medicare policy would be \$122 million each year.

The taxpayer costs of the current Medicare limitations could become even higher with the wider use of Zemplar, a drug costing twice as much as Calcijex. If all patients currently using Calcijex were prescribed Zemplar instead, Medicare could see an increase to \$317 million in the annual cost of covering vitamin D hormones. Were this to occur, reforming Medicare policy to cover Hectorol could save American taxpayers as much as \$272 million each year (see Figure 2).

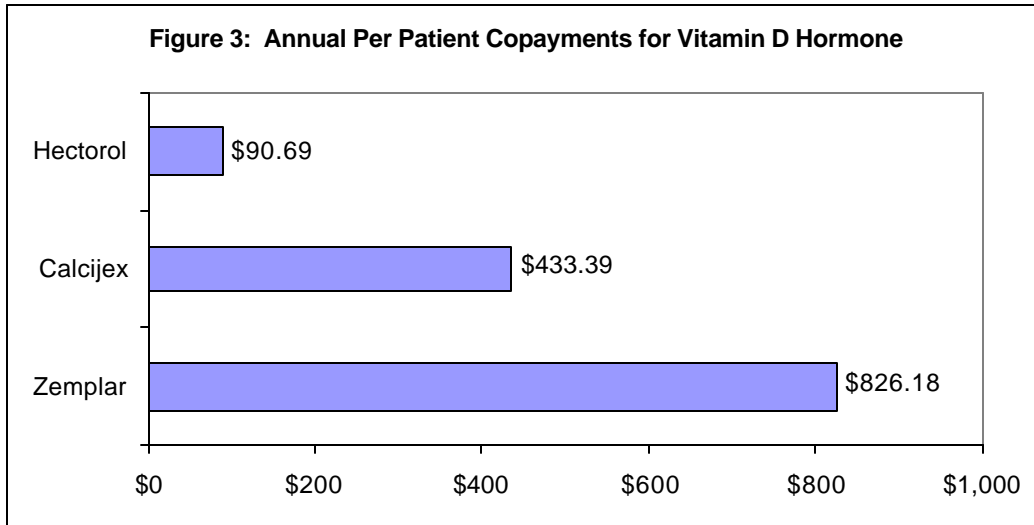


V. THE COST TO KIDNEY PATIENTS

For drugs covered under Medicare, patients are required to pay 20% of the drug's cost. (For some ESRD patients, this copayment is covered under a private insurance plan.) Because only expensive, injectable vitamin D hormones are covered by Medicare, patients and insurers are forced to pay a higher copayment than if patients were simply prescribed an oral form of vitamin D hormone.

This study estimated that each patient who uses Calcijex spends \$433.99 each year on Medicare copayments. If Medicare were to cover Hectorol, each patient who switched from Calcijex to Hectorol would find his or her annual copayments dropping to \$90.69, for a savings of \$343.30 each year. As discussed above, there may be as many as 101,000 ESRD patients using Calcijex. If these patients were able to receive Medicare reimbursement for Hectorol, the potential savings for all patients would be as much as \$35 million each year.

These potential cost savings will increase in coming years as patients currently using Calcijex are prescribed Zemplar instead. A patient's annual copayment for Zemplar is \$826.18, or more than nine times the hypothetical copayment for Hectorol. Thus, if federal policy were changed to allow Medicare coverage of Hectorol, patients using Zemplar could save \$735.49 annually in copayments by switching to Hectorol. Nationwide, the savings could be as much \$74 million each year (see Figure 3).



VI. THE IMPACT ON DRUG MANUFACTURERS

Not only does the current federal policy waste government and patient money, it unduly benefits Abbott Laboratories, the manufacturer of Calcijex and Zemplar, at the expense of Bone Care International, the manufacturer of Hectorol, even though both drugs are therapeutically equivalent. The current policy has created a perverse incentive system that actually discourages pharmaceutical companies from trying to develop lower-cost drugs. Indeed, no matter how inexpensively Hectorol is priced, Bone Care cannot hope to capture a greater share of the vitamin D hormone market as long as federal law allows Medicare to cover only one version of the drug.

In addition, the current federal policy reduces the incentive for pharmaceutical companies to conduct research on certain types of drugs. There is presently little financial incentive for a manufacturer to expend significant resources to improve the oral form of vitamin D hormone. The existing market for the oral drug is too small to justify the research time and money needed for such an endeavor. Nevertheless, bone disease is a problem not limited to ESRD patients, since many elderly patients also suffer from this condition. While Hectorol is intended for use by ESRD patients, improvements in this drug could potentially benefit a larger population of persons with bone disease. A change in the current policy might thus have the additional positive effect of spurring pharmaceutical companies to become more innovative in this area of drug research.

Appendix
Calculation of Annual, Per-Patient Cost for Different Versions of Vitamin D Hormone

To calculate the annual, per-patient cost for the three versions of vitamin D hormone, this study used the lowest, recommended maintenance dosage for each drug and the average wholesale price (AWP) for each drug.¹⁷

To calculate the actual cost to Medicare for these drugs, the estimated annual, per-patient cost for each drug was adjusted for two factors. First, Medicare only reimburses providers 95% of a drug's AWP. Second, Medicare only pays 80% of a drug's cost, requiring the patient to make a 20% copayment.

Hectorol – The recommended maintenance dosage of Hectorol is 10 mcg to 20 mcg per week. The drug is offered in a 2.5 mcg capsule, which has an AWP of \$2.18. The weekly cost of the drug based on the lowest recommended dosage is \$8.72, and the annual cost is \$453.44. The actual, per-patient cost to Medicare each year is \$344.61 ($\$453.44 \times .95 \times .8$).

Calcijex – The recommended maintenance dosage of Calcijex is 1 mcg to 2 mcg three times a week, with subsequent dosages up to 4 mcg three times a week. The drug is offered in a 1 mcg/ml vial, which has an AWP of \$13.91. The weekly cost of the drug (based on the lowest, recommended maintenance dosage) is \$41.73, and the annual cost is \$2,169.96. The actual, per-patient cost to Medicare each year is \$1,649.17 ($\$2,169.96 \times .95 \times .8$).

Zemplar – The recommended maintenance dosage of Zemplar is 2.8 mcg to 7 mcg three times a week, with subsequent dosages up to 16.8 mcg three times a week. The drug is offered in a 5 mcg/ml vial, which has an AWP of \$26.48. The weekly cost of the drug (based on the lowest, recommended maintenance dosage) is \$79.44, and the annual cost is \$4,130.88.¹⁸ The actual, per-patient cost to Medicare each year is \$3,139.47 ($\$4,130.88 \times .95 \times .8$).

¹⁷The AWP is based on cost figures published by First Data Bank (Feb. 23, 2000).

¹⁸Although patients taking 2.8 mcg of Zemplar would only use a portion of a 5 mcg/ml vial of Zemplar, the remainder of the drug is discarded.