

Generics

# GENERIC DRUGS:

The business of practicing good medicine

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A roundtable discussion

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## The business of practicing good medicine

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Sharing a life and home with a pet is an emotionally rewarding opportunity. Unfortunately, when pets become ill, clients experience both emotional and financial costs. While we, as veterinarians and veterinary staff members, strive to provide the best possible care for our patients, the amount of disposable income that an individual client has for their pet's care may not always meet the pet's medical needs. One way to help these situations without cutting corners may be to provide the same quality—but less costly—medications.

### Definition of generic drugs

**Dr. Margie Scherk:** How do you define the term generic drug?

**Dr. Margo Karriker:** A generic drug is a pharmacologic agent approved by the Food & Drug Administration (FDA) as a bioequivalent substitute and manufactured by a number of different companies as a result of the expiration of the original patent.

**Dr. Peter H. Rheinstein:** The FDA approves generic drugs the same way as brand-name drugs, except in place of the brand-name drug's efficacy studies, researchers conduct a bioequivalence study, which shows that the generic drug works the same way as the pioneer drug. With veterinary drugs in the United States, you can tell it is a generic if it has an application number that begins with 2.

**Dr. James Olson:** In veterinary school, we were taught that generics were the same as the brand-name drugs. We were forced to learn scientific names because we knew that at some point, a generic would be released. For example, we used to administer benazepril as the brand-name drug Lotensin. As soon as it went generic the price decreased, which caused our clients to better comply with our recommendations. Generics are the way to go.

**Gary Glassman:** A lot of people define generics based upon them being less expensive—not their bioequivalency and active ingredients.

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**Scherk:** That gives us peace of mind that what we are buying is bioequivalency. We can rest assured that generics are bioequivalent and just as efficacious as the original patented brand names.

**Advantages of generics**

**Scherk:** Why should a practice carry generic drugs?

**Glassman:** Practitioners like alternatives. They see a variety of clients and pets with varying needs. Generics offer a prescribing alternative and help clients comply with their veterinarian’s recommendations and follow a particular medical protocol. Cost is always an issue in veterinary medicine. The general public may perceive pets’ health-care to be expensive because insurance cost supplements don’t usually exist. In human medicine the office visit co-pay may be \$20, while the veterinary visit may seem to cost much more.

We need to have generics available that are equivalent to brand-name drugs and that can address the cost issue. The only downside is that veterinarians sometimes offer alternative treatments for pets based on what they think the client can afford—for example, offering something to alleviate an ailment instead of doing a complete workup, or worse, doing nothing at all. The lower cost of generics might enable the veterinarian to offer medication immediately.

**Karriker:** Carrying generic drugs can help keep the medication distribution process in the practice so the practice team stays on top of the treatment plan. It also enables practitioners to offer the best drug information when clients come in for medications and have questions about their pet’s medications. This helps get important information to clients from the professionals who know the most about veterinary drugs and their pet.

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## Advantages of generic veterinary drugs

- Are bioequivalent to brand-name drugs
- Cost less than brand-name drugs
- Offer alternatives to practitioners
- Enhance client compliance
- Create competition in the market

**Olson:** Once a patent expires and a drug goes generic, it creates prescribing options and competition, which drives down prices. The lower cost may, in turn increase pet owner compliance.

**Rheinstein:** The constitution gives Congress the power to enact patent laws using the phrase “for a limited time.” The idea that a drug becomes generic after a period of time stimulates companies to create new products.

### Safety and efficacy

**Scherk:** How do veterinarians know that the generic will be as effective and safe as the brand-name drug?

**Rheinstein:** First, practitioners must be sure it really is a generic and not a compounded product. If it is an FDA-approved generic, they know it has been through the same process as the pioneer drug. This is true of both veterinary and human generic drugs. They know that the only difference is that a bioequivalence study was done in place of a new clinical trial; the bioequivalence study proves that the generic drug delivers to the bloodstream or to the site of activity the same ingredient, in the same amount, and at the same rate as the pioneer drug. The generic drug thus will have the same effect as the pioneer drug. A summary of each trial conducted for veterinary products is posted on the FDA’s Center for Veterinary Medicine (CVM) website at [www.fda.gov/cvm/FOI/foidocs.htm](http://www.fda.gov/cvm/FOI/foidocs.htm).

**Scherk:** For both generic and brand-name drugs, Health Canada conducts spot checks

of different batches and monitors that they are the same.

**Rheinstein:** The FDA requires the same thing for brand-name and generic drugs—but the manufacturers are responsible for monitoring the batches.

**Scherk:** We not only know that generic drugs go through bioequivalency studies and licensing, but also that the drugs are being monitored. That is a good assurance of safety and quality.

Some people have expressed concern that generic drugs may be manufactured overseas in developing countries with little oversight. How do you respond to that?

**Rheinstein:** The active pharmaceutical ingredients of both brand-name and generic drugs are more likely than not to be manufactured overseas. For that reason, the FDA has a cadre of inspectors who are sent to manufacturing facilities all over the world. The same inspectors use the same guidelines for both human and animal drugs. Approval of a product—either a brand or generic—indicates the plant that manufactured it has been inspected and will continue to be inspected at regular intervals.

**Scherk:** So can you feel just as safe dispensing generics as you can brand-name drugs?

**Rheinstein:** Yes, the FDA has worked very hard to make that the case. The inspectors are the same for both brand name and generic drugs.

**Scherk:** I think veterinarians would like to know what generic drug companies are responsible for in terms of pharmacovigilance. The fact is that whenever a drug company—generic or brand name manufacturer—learns of an adverse event, they investigate and report it to the CVM, as required by law. The regulations are the same for all pharmaceutical companies.



“The first place to go for information on the availability of FDA-approved human or veterinary products is the FDA website.”

— Dr. Margo Karriker

**Rheinstein:** Yes, the regulations are the same. That is one reason why practitioners need to keep accurate records as to the source of the product they dispense.

### When to carry generics

**Scherk:** In my opinion, because we have bioequivalency data, I don't see any reason to carry brand names when a generic exists.

**Olson:** As a practitioner, I agree.

**Scherk:** If a generic exists, I don't think we do our clients a service by giving them a choice when prescribing medications. They don't have the knowledge to make that decision. That is why they come to us, for our expertise and knowledge.

**Glassman:** You're right. Clients usually aren't in a position to determine what is best for their pet—that's why they take their pet to a veterinarian. Veterinarians many times give clients alternatives without providing them with enough education to make the right decision. I think veterinarians should have alternatives available, but they should make the choice.

**Karriker:** I disagree. From the human side, I think clients can be well enough informed to know that branded and generic products are equivalent. In most clinical situations, the use of a generic product is not significant, with the exception of economics. Brand and generic switches happen all the time in human pharmacies. For example, if a prescription is written for Brand X and “Dispense as written” is not noted on the face of the prescription, many states allow for the client to choose the generic or the brand-name product as they desire. There are situations when a client prefers a choice of products.

The problem in veterinary medicine is that veterinary-labeled products are generally only sold through licensed veterinarians. If the client wants choices, they should be available. Unfortunately, for a veterinary practice's bottom line, if you don't dispense a large volume of the brand-name product, then a lot of expensive drugs may be left on your shelf.

**Glassman:** I am not suggesting that clients are not intelligent enough to make a decision. But how can they gain enough information in a short period of time to make the decision based on anything other than price?

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## FDA resources

- Electronic Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations ([www.fda.gov/cder/ob](http://www.fda.gov/cder/ob))
- FDA Approved Animal Drug Products: Green Book ([www.fda.gov/cvm/greenbook.html](http://www.fda.gov/cvm/greenbook.html))
- FDA Veterinarian newsletter ([www.fda.gov/cvm/fdavetfrm.htm](http://www.fda.gov/cvm/fdavetfrm.htm))

**Rheinstein:** In human medicine, some people are used to a particular trade name and appearance or taste. They may be willing to pay extra for that satisfaction.

**Scherk:** If a client comes from a different practice and was getting a human brand-name drug that you don't carry, there is no reason why you can't write a prescription and have the pharmacist fill that brand name for those few situations.

**Olson:** In my years of practice, the more options I give my clients, the more confused they get. Even when I go to a doctor, I ask the doctor what he or she would do. I reverse that on my clients. I say, "If this were my cat, this is exactly what I would do, and these are the drugs that I would use." Then I give them the reasons why. I don't talk about cost—I like to treat the patient the best way I can. If it is a win-win situation for yourself and the patient, then everybody smiles at the end.

**Glassman:** You made a very interesting comment. You look after what is best for the pet and client and don't even talk about money, which is great. You suggest the best medical approach before talking about anything else. Some veterinarians may not necessarily suggest the best option up front but instead look at clients from the perspective of what resources they have.

**Olson:** Yes, I've taken myself out of the

money conversations. I can't tell you what we charge for a spay in our practice. My technicians handle that because once you start negotiating price, you can make bad choices.

**Glassman:** We can't lose sight of that. Veterinarians need to look at the operational aspect of their practice and consider—before talking with clients—whether they want to offer drug choices. They will need to limit the number of drugs they carry—they can't go overboard. When it comes to any particular drug, there may be three branded products and seven generic bioequivalent products that could solve the same problem. Do they carry all 10, or do they narrow that down and only carry two or three? The cost of carrying all of these drugs becomes a huge financial burden and it's inefficient for the practice.

**Karriker:** That's a great plan. You can maximize your inventory with just a few options. The easiest way to approach these issues is to know all the medication options available and to consider the factors (financial and otherwise) that dictate the medication choices for the patients of a particular practice.

## Generic availability and dosages

**Scherk:** How do veterinarians determine if a product is available as a generic?

**Karriker:** We have many resources available to us. The first place to go for information on the availability of FDA-approved human or veterinary products is the FDA website. Just go to the FDA's main page and the CVM's home page and look for the Orange Book (human drugs) and Green Book (veterinary drugs), which are updated daily and monthly, respectively. They are easily searchable by the active ingredient, sponsor's name, and brand names. The Orange Book for human-approved drugs even includes discontinued products. You can also subscribe to the FDA veterinarian newsletter.

**Table 1. Managing your inventory for greater profitability**

Prepared by Gary Glassman, CPA

	<b>Non-shopped and non-exposed products</b>	<b>Shopped and exposed products</b>
<b>Markup</b>	2.5 x cost (150%)	2 x cost (100%)
Dispensing fee	Yes	No
Subject to a minimum pre-prescription price	Yes	No

**Rheinstein:** Yes, the Orange Book and Green Book are easy to search.

**Scherk:** If I want to know if a human generic is available, I call my pharmacist. My pharmacist is my partner, just as the pathologist is my partner. You have to use each other as resources because we are not pharmacists.

**Karriker:** Pharmacists are a great resource for information on generic drugs. It is important to keep in mind that many pharmacists, outside of academic veterinary medicine and veterinary specialty pharmacies, may not be familiar with veterinary-labeled drugs and their generic equivalents, as these drugs are not commonly encountered in a human pharmacy practice.

I think a partnership approach with your local pharmacist is a great way to utilize expertise in both pharmacy and veterinary medicine to get the most comprehensive information.

**Rheinstein:** Another thing to remember for a practice is that even if a generic is approved, it is probably not available to you unless your distributor carries it.

**Karriker:** It can be difficult to keep up with what's available. The person who does purchasing in most veterinary practices gets a lot of information from distributors and

wholesalers, but the reality is that information really comes from many sources, including the manufacturer, advertising, the Internet and other direct-to-consumer resources.

**Scherk:** What generic drugs do you use in your practice?

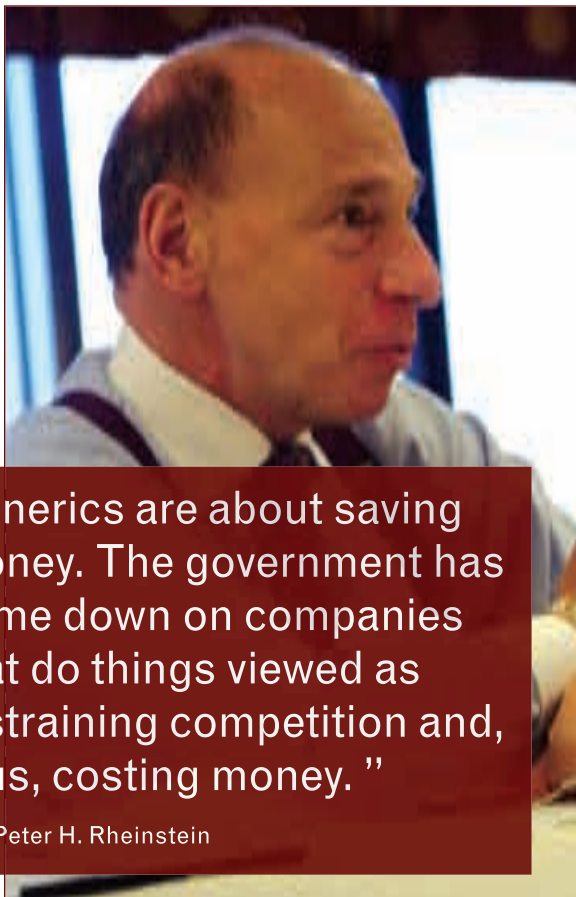
**Olson:** I use as many generics as I can: amlodipine, benazepril, atenolol, tylosin, metronidazole, prednisolone, and dexamethasone. There are fewer approved drugs for cats, so practitioners turn more often to human generics for prescribing options.

**Scherk:** Assuming the formulation and strength are suitable for cats, I use generics whenever one is available. It can be confusing, though, because some veterinary generics have names that make you think they're brand-name drugs. For example, Triheart and Iverhart are named generics, while Heartgard is the brand-name drug. Another example is carprofen. Rimadyl is the brand name, and Novox is a generic with a trade name, rather than labeled with the active ingredient as human generics are labeled.

In addition, if we're talking about true bioequivalent generics, then if the brand name is available in a 20-mg dose, the generic will be available in a 20-mg dose. One may be blue and the other may be pink, or one may be chicken flavored and the other

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“Generics are about saving money. The government has come down on companies that do things viewed as restraining competition and, thus, costing money.”

— Dr. Peter H. Rheinstein

liver, but they will be equivalent in dose form, strength, and formulation.

**Rheinstein:** A provision in the law allows the approval of Abbreviated New Animal Drug Application (ANADA) eligibility petitions. If a company offers 10-mg and 20-mg chewables, a would-be applicant can petition the CVM and ask that a 15-mg dosage be considered ANADA eligible. During the bioequivalence trials, the FDA doesn't require a company to check every dosage—it might require bioequivalence for the highest and lowest doses. So it is conceivable that you could have a bioequivalent generic that is actually an intermediate strength between two dosage strengths marketed by the pioneer manufacturer.

**Scherk:** That might be a more usable patient-sized dose.

## Impact on revenue

**Scherk:** Can generic drugs help practices protect pharmacy revenues?

**Glassman:** Yes, they can. Generics tend to be less expensive and enable veterinarians to gain client compliance because they are less likely to skip doses to save money. If clients continue to accept our recommendations, then we will keep the revenue that is generated through refills. Pharmacy revenue is the most vulnerable type of revenue that a practice generates because of all the competing sources.

**Olson:** Internet pharmacies and catalog houses all try to compete with us to take pharmacy revenues from our practice. Pharmacy, over-the-counter, and prescription food revenue makes up about 30% of a practice's gross revenue. So almost one-third of your revenue comes not from the provision of veterinary services but from product sales.

We should think about the fact that our pharmacy is a revenue source—yet we may not consider it to be as important as providing veterinary care. If we think about what we do in our hospitals that isn't profitable, we either have to change our mentality about charging more or we need to realize that the highly profitable areas within our practice (*e.g.*, pharmacy sales or diagnostics) allow us to do many things that aren't as profitable.

So should we pay attention to our pharmacy sales? Yes, we should. Veterinary expenses are basically fixed—they don't change whether we sell one particular pharmacy item or another. But the sale of that prescription helps cover those expenses and adds a significant amount of profitability. It is extremely important for us to look at how the sale of pharmaceutical items affects overall profitability.

**Karriker:** Veterinarians need to realize the importance of pharmacy sales and medication-related services. We want to provide everything

**Table 2. Use of dispensing fees and minimum Rx prices**

Prepared by Gary Glassman, CPA

<b>Product X</b>	<b>Example 1</b>	<b>Example 2</b>
Quantity sold	10	25
Sales price	<u>x 0.45</u>	<u>x 0.45</u>
	\$4.50	\$11.25
Dispensing fee	<u>+ 8.00</u>	<u>+ 8.00</u>
	<b>\$12.50</b>	<b>\$19.25</b>
Minimum prescription price	\$14.00	\$14.00
Sales price to client	\$14.00	\$19.25

**Table 3. Improved compliance leads to greater profits**

Prepared by Gary Glassman, CPA

<b>Product Y</b>	<b>Branded drug</b>	<b>Generic drug</b>
Quantity sold per month	1,000	2,500
Sales price	<u>x \$2.50</u>	<u>x \$1.25</u>
	\$2,500	\$3,125
Cost (Markup of 2.5)	<u>- 1,000</u>	<u>- 1,250</u>
<b>Profit</b>	<b>\$1,500</b>	<b>\$1,875</b>

Profit margin difference: \$375/month x 12 = \$4,500/year

Profitability improvement: 25%

that an outside pharmacy would, including reminder systems, quality assurance checks, and convenient, quality products and services. Veterinary practices can take a look at the pharmacy services they provide and see how they measure up to the competition in terms of safety, quality, cost-effectiveness, and convenience. We have to focus on providing high-quality pharmacy services so we can depend on those revenues for years to come.

**Scherk:** Dr. Rheinstein, how do you think generic drugs can help practices protect pharmacy revenues?

**Rheinstein:** A convenience factor exists. It is incredibly convenient to go to one place

to have the medication in hand, formulated for your pet, and in the right dose for your pet. Generics are all about saving money. The U.S. government has come down on companies that do things viewed as restraining competition and, thus, costing money.

When I was a kid, only ophthalmologists and optometrists sold glasses. Ultimately, the Federal Trade Commission stepped in and said we needed competition to decrease the cost of glasses and contact lenses—ophthalmologists and optometrists were no longer allowed to make it difficult for people to get their prescriptions. Then the price of contact lenses decreased dramatically.

**Karriker:** That's a good point. We can't make it difficult for clients. Most states clearly

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delineate that we must offer clients prescriptions that they can fill outside our hospitals. However, if they fill the prescription at our hospital, we can help keep track of the medications. We can help guide them on how to give the medications to their pet, what adverse events to expect, and how to deal with medication interactions, and we can provide other information that they can't get somewhere else. So offering generics not only provides an affordable option to the client but also helps keep the prescription in the clinic.

**Olson:** Yes, it's difficult to track written prescriptions. I'm considering charging clients who want outside prescriptions because it takes so much time to follow it in the medical record.

**Scherk:** So by having generics in your practice—because they cost less—clients may be more likely to stick with the dosing regimen and continue refilling the prescription with you. Certainly they can get their prescriptions filled somewhere else, but it won't be cheaper.

## How to price generics

**Scherk:** How should practices price generic drugs?

**Glassman:** The typical pricing model in a veterinary hospital is to set a standard markup and add a dispensing fee to determine a minimum prescription price (see *Table 1*, page 7). This allows low quantities of dispensed medications to still drive enough of a profit margin for the hospital. A minimum prescription price should also be in place for all items that are repackaged (counted and labeled). This allows low quantities of repackaged dispensed medications to still earn enough of a profit for the hospital (see *Tables 2* and *3*, page 9).

Most veterinary software programs include fields that allow you to define a sales markup percentage, dispensing fee, and minimum prescription price. As long as you set the parameters, the sale price

will automatically be calculated without the practitioner manually calculating them.

**Karriker:** We use the same pricing model, but we add a scaled markup instead of just a flat markup. A higher markup exists for lower-cost items, and a lower markup exists for higher-cost items. Especially as we become more generic-heavy and medication costs decrease, we make more profit and it's a lower, overall price for the client. Some specialty medications can cost several hundred dollars for one dose and because clients shop around for these high-priced items, we use a lower markup to keep the price to the client low enough to be competitive with outside sources.

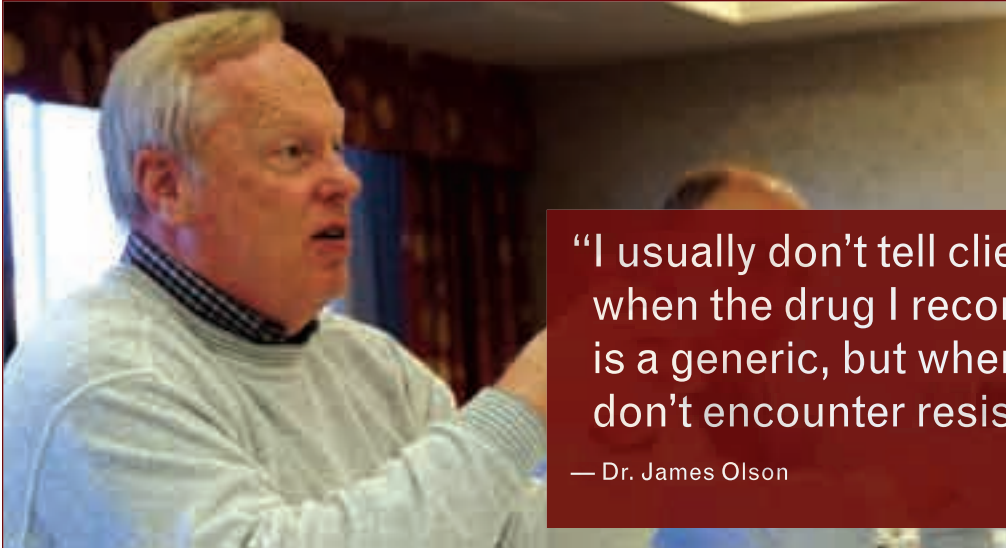
**Glassman:** It's common for practitioners to be very sensitive about pricing or using different markups based upon the product.

**Karriker:** We separate our medications by class—injections, oral medications, flea-tick-heartworm medications, and higher-priced oncology or specialty medications—and use a separate pricing scale for each classification. This allows for easy separation of pricing data according to the needs of a particular type of medication and its preparation for dispensing or administration. For example, injections generally require more packaging and administration time, so they have a higher dispensing fee, while oral formulations have a lower dispensing fee. Inventory control is much easier in most databases if some classifications are set up front.

## Client compliance with generics

**Scherk:** How do pet owners respond to veterinarians' recommendations when generic drugs are dispensed?

**Glassman:** I listen to whatever my veterinarian says. If my veterinarian tells me this drug is recommended to manage my pet's problem, then I listen.



“I usually don’t tell clients when the drug I recommend is a generic, but when I do, I don’t encounter resistance.”

— Dr. James Olson

**Olson:** I usually don’t tell my clients when the drug I recommend is a generic, but when I do, I don’t encounter resistance. But when dealing with confrontational clients who don’t initially comply, I use a sales technique called reversal. I say, “What do you want me to do?” Then I listen to them and either say, “I can do that,” or “I can’t do that. That doesn’t make a lot of sense medically.” Usually when I use that type of questioning, clients accept the recommendation.

**Glassman:** I think the problem is that we’re a society of information overload. Most information available to clients is not good information. You’re the doctor, but clients come to you only after conducting a ton of research. Being able to determine what is good vs. bad information helps clients reach a conclusion that makes sense.

**Scherk:** All relationships within a veterinary clinic are based on trust. I’ve never had a client ask me about a generic vs. a brand-name drug.

What are your perceptions about clients’ experiences with generic drugs?

**Rheinstein:** My wife takes our dog to the veterinarian. If the veterinarian tries to sell her a medication or service that is different

from what she has had previously, she will ask for an explanation. She will want assurance that the recommended pills are as safe and efficacious as the ones we have used in the past.

**Karriker:** I generally wouldn’t question my veterinarian if he or she recommended a generic over a brand-name drug as I have established a level of trust in the doctor’s professional judgment. However, I have seen owners who are swayed by their own experiences with brand-name or generic drugs. Some clients have had bad experiences or want a certain product before they come to your practice. In cases like this, it can be difficult to change their mind.

**Rheinstein:** Because the government pays for a hefty percentage of human medicines, the FDA spends money educating people about human generic drugs. But the FDA does not spend money to educate people about generic veterinary drugs.

**Scherk:** Giving clients the option of buying generic drugs can make the difference between them filling the prescription or leaving without it. For example, a situation may arise when a generic costs \$20 vs. a \$120 brand-name drug, making the

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## Animal Medicinal Drug Use Clarification Act of 1994 (AMDUCA)

AMDUCA allows veterinarians to prescribe extra-label uses of certain approved animal drugs and approved human drugs for their patients. Although some restrictions apply to veterinarians prescribing animal and human drugs in an extra-label manner, these restrictions generally concern the extra-label use of drugs in food-producing animals.

The key constraints of AMDUCA are that any extra-label use must be by or on the order of a veterinarian within the context of a veterinarian-client-patient relationship, must not result in violative residues in food-producing animals, and must conform to regulations published at 21 CFR Part 530 ([www.fda.gov/cvm/Documents/530.pdf](http://www.fda.gov/cvm/Documents/530.pdf)). A list of drugs prohibited from extra-label use ([www.fda.gov/cvm/Documents/530\\_41.pdf](http://www.fda.gov/cvm/Documents/530_41.pdf)) appears in the Code of Federal Regulations.

client unable or unwilling to buy the more expensive medication.

**Glassman:** I agree, but monetary issues may be an overriding factor regardless of what is prescribed. Most veterinarians will try to offer options. A client would be hard pressed to leave a practice without any drug at all if he or she had explored all the options. One way or another, the issues are resolved if a client is truly interested in pursuing treatment.

**Karriker:** Drug therapy is similar to other parts of the care process. We may not use our drug of choice or therapy of choice, but in most cases we can find something that will fit the client and patient.

**Scherk:** Yes, even if we say, "Let's see how he does overnight. We'll call you tomorrow." Then if he is not doing better, the client is

further motivated to accept the medication recommendation.

So what about a patient with a chronic illness, such as renal insufficiency, arthritis, or inflammatory bowel disease, which requires long-term drug therapy? What role can generic drugs play in treating these chronic diseases, and do you think you might expect compliance to increase if a generic is available?

**Karriker:** Chronic cases often require multiple medications. The longer the disease state persists, the more medication options you may have to add. If the generic is more cost-effective, then we may be able to add other drugs or adjunct therapy, and still have an overall cost-effective treatment plan. We would have more flexibility with the finite dollars that clients are able to spend.

**Scherk:** Yes, especially with chronic illness, cost can become an emotional as well as financial burden. Having a less expensive option may be a huge benefit. In addition, pet insurance covers a maximum amount per condition. For my clients with pet insurance, utilizing generic drugs means that the insurance will cover a longer treatment period for that patient.

## Communication with clients

**Scherk:** If we dispense human-approved generics for extralabel use, what are we ethically and legally required to communicate to clients, and what record-keeping is required?

**Rheinstein:** The Animal Medicinal Drug Use Clarification Act (AMDUCA) sets these guidelines, and you can access the requirements on the FDA website (see *Animal Medicinal Drug Use Clarification Act of 1994*).

**Scherk:** Can you just write down the chemical name in the record?

**Karriker:** If you dispense a generic, the chemical name works. But in the case of Heartgard, Triheart, and Iverheart, if you only wrote down the chemical name of ivermectin, you

wouldn't know which product was used. As it is with most legal issues, the rule of thumb is to write everything out. Give clients as much information as you can and write everything in the record, including the reason for your decision to choose one product over the other. When a client walks away with a medication, anyone should be able to pick up the medical record or medication label and know exactly what product was used without question.

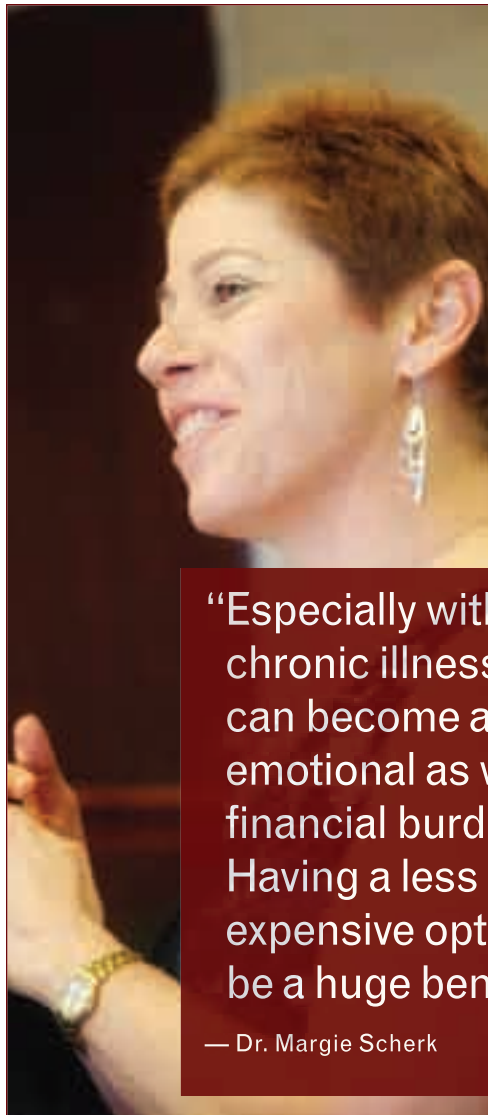
**Scherk:** According to the AMDUCA, we should write on the label as well as in the medical record that we are using, for instance, metronidazole and then in parentheses, we should write Flagyl. If we were using generic metronidazole, that's all we would list.

**Karriker:** Absolutely. You also must make sure that your labels are correct and you track your inventory. When you try to go back and reconstruct your records, it can be quite difficult without comprehensive information. Medication recalls and other issues can be very problematic without proper documentation of medications that each patient received.

**Rheinstein:** It is also enormously helpful to the FDA and other agencies if you keep a record of the source of products that you dispense. If there is a problem that the agency needs to follow up on, there's no way to do it without knowing the source of the product.

**Scherk:** How about getting owners' consent: Do you have them sign a form, or do you rely on verbal approval?

**Karriker:** The legal debate is about whether this accomplishes anything. Does it add to your case legally if the client signs a piece of paper that says we dispensed a human-approved drug? Arguments can be made that it doesn't add anything because loopholes always exist when communicating information about complex issues. Often,



“Especially with chronic illness, costs can become an emotional as well as financial burden. Having a less expensive option can be a huge benefit.”

— Dr. Margie Scherk

the best solution is to have open communication in a way that works for your practice and clients.

**Scherk:** Exactly. Clients can always say they didn't understand what they were signing. The other thing, too, is that if you have them sign something, they will wonder about whether it is safe. It's a double-edged sword.

### Extralabel uses

**Scherk:** What do veterinarians need to keep in mind when prescribing human-approved generic drugs for extralabel use?

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“A client would be hard pressed to leave a practice without any drug at all if he or she had explored all the options.”

— Gary Glassman



**Karriker:** Some drugs are available as human generics when we only have a branded veterinary product. One example is marbofloxacin. An additional liability may exist when we choose a human product to use extralabel when we have an approved veterinary drug. Generally, we would need strong evidence to explain why we chose a human-approved product, based on something other than cost.

**Scherk:** In Europe, if a product is labeled for veterinary use, you have to choose that one. Veterinarians can use a human generic drug only when one for veterinary use doesn't exist.

**Rheinstein:** It is important to remember that bioequivalence is determined by species. To have a veterinary generic approved if the pioneer drug is approved in cats and dogs, you must conduct the bioequivalence trials in cats and dogs. If you use a human generic extralabel in animals, you need to remember that the bioequivalence was established for people and it may or may not apply to another animal species. You must see if it works in the species you treat—the product may pass through the digestive system differently.

Furthermore, if you use a human generic drug in an animal and the result is bad, and

the client sues, the plaintiff's attorney can bring up anything to sway the court. So the line of questioning could be, “Doctor, does a veterinary-approved formulation of this drug exist? Did you use it?” Then the plaintiff's attorney could point out the drug you used had not been tested in animals even though another formulation that had been proven in animals was available. This argument may not increase your liability, but it may increase the chances that a judge or a jury would rule against you.

## Compounded drugs

**Scherk:** What are the differences between generic and compounded drugs?

**Olson:** A difference may exist in quality control. When you compound a drug, it is not FDA-approved, and you can't prove its bioequivalence or efficacy.

**Scherk:** Do people understand that compounded drugs are not the same as generics?

**Karriker:** The awareness has grown about compounded medications. We should clarify that no matter how compounded products are marketed or how they look when they arrive at our practice, they are not generic drugs. In my opinion, the controls necessary

to ensure safety, efficacy, stability, potency, and security may not be in place with compounded drugs and may vary based on the compounding pharmacy. Compounding pharmacy practice has made many strides toward providing high-quality products; however, it is important to remember that there is an appropriate place for them in therapy. The intent of compounding is not to duplicate the drugs we have on the commercial side but to fill therapeutic gaps that exist for individual patients. It's the same in human medicine.

A couple of ongoing efforts exist to set compounding standards. It is in the interest of compounding pharmacies to have their peer group produce quality products across the board. They made an effort to set standards and have trained pharmacists. The standards set for a commercial pharmaceutical company are still very different. It's important for veterinarians to talk about compounded products and make sure they are used correctly.

**Scherk:** You mentioned two important points. First, regarding the stability and potency of compounded products, just because you can physically put a drug into a flavored liquid does not mean it will be stable for the duration of therapy.

Similarly, the potency may be altered by the reformulation. Veterinarians need to ask these questions and request data from the compounding pharmacists. Some of that data is available from the International College of Veterinary Pharmacists or the American College of Apothecaries.

**Karriker:** Rules published in the United States Pharmacopeia National Formulary list what you have to do to prove the product's potency and stability. It is also important for efficacy—just because there is 50 mg/ml in a product doesn't mean that the drug gets to the intended tissue. Many pharmacokinetic and pharmacodynamic factors must be considered when manipulating a drug or altering the dosage form.

**Scherk:** This is important to know because with generic drugs, the stability and potency have been evaluated and FDA-approved, just like the brand-name drugs.

**Karriker:** Although compounded products might start with an approved active ingredient or an approved brand-name or generic drug, the minute you alter it, all bets are off and the previous FDA oversight for product assurance of potency or stability no longer exists.

**Rheinstein:** That's right. When you are dealing with an FDA-approved brand-name or generic, stability and potency are ensured. When you are dealing with a compounded product, you are simply asking the pharmacist to put certain ingredients together. So if your choice is between using an approved human generic extralabel or using a compounded product, you should use the human generic extralabel because potency, stability, and quality testing are ensured.

**Karriker:** Consistency is a large part of it, too. You can have a myriad of different ingredients, and each pharmacy may formulate the same drug differently.

## Conclusion

**Scherk:** Do you wish to make any final comments?

**Olson:** To summarize, generics come down to four things. First, in terms of economics, generics are a win-win situation for my practice and clients. Second, they are bioequivalent to brand-name drugs. Third, the quality control and consistency are ensured. Finally, they work. This will be evident very quickly when practitioners use the drugs. The quality control assurance is what veterinarians want most—quality control is what the FDA provides.

**Scherk:** Thank you all for your participation today. I hope this discussion has provided useful education about what generics are and what they are not.

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