

The case for “pour & count” pharmaceutical packaging



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THIS ARTICLE will compare the two major delivery systems for prescription drugs, namely the “pour and count” (P&C) system generally used in the United States and Canada, and the “unit of use” (UOU) system found in Europe and other parts of the world. P&C is typically seen as the plastic vials obtained at the retail pharmacy; UOU (also known as “unit dose”) features a foil or multilayer blister packaging for individual pills. We contend that the P&C system offers economic and flexibility advantages over UOU.

United States & Canada

The P&C system is used by retail outlets to fill the vast majority of prescriptions (Rx) in the U.S. and Canada. Retail outlets include independent drug stores, chain drug stores, grocery chains, and mass merchants. For

purposes of this article, mail order and hospitals are ignored. The supply chain distribution system for delivery of the drugs from the pharmaceutical manufacturer to the consumer generally consists of four steps:

1) The manufacturer packages the tablets and capsules in large bulk packs, typically ranging from 100 to 1000 pills or more per bottle and the bulk packs are shipped to distributors in mass caseload quantities.

2) The distributors ship small quantities of these bulk-pack bottles to the individual retailers on demand.

3) The retailer fills a consumer’s prescription by “pouring” a number of pills out of the bottle and “counting” to exact amount of the prescription order.

4) The retailer then places the pills in a custom-labeled vial for the consumer. Many pharmacies have automated the P&C process with robotics to minimize labor and improve counting accuracy.

Europe

In Europe, the UOU system is used for most of the prescription pills. Although the distribution system is essentially the same as in the U.S. and

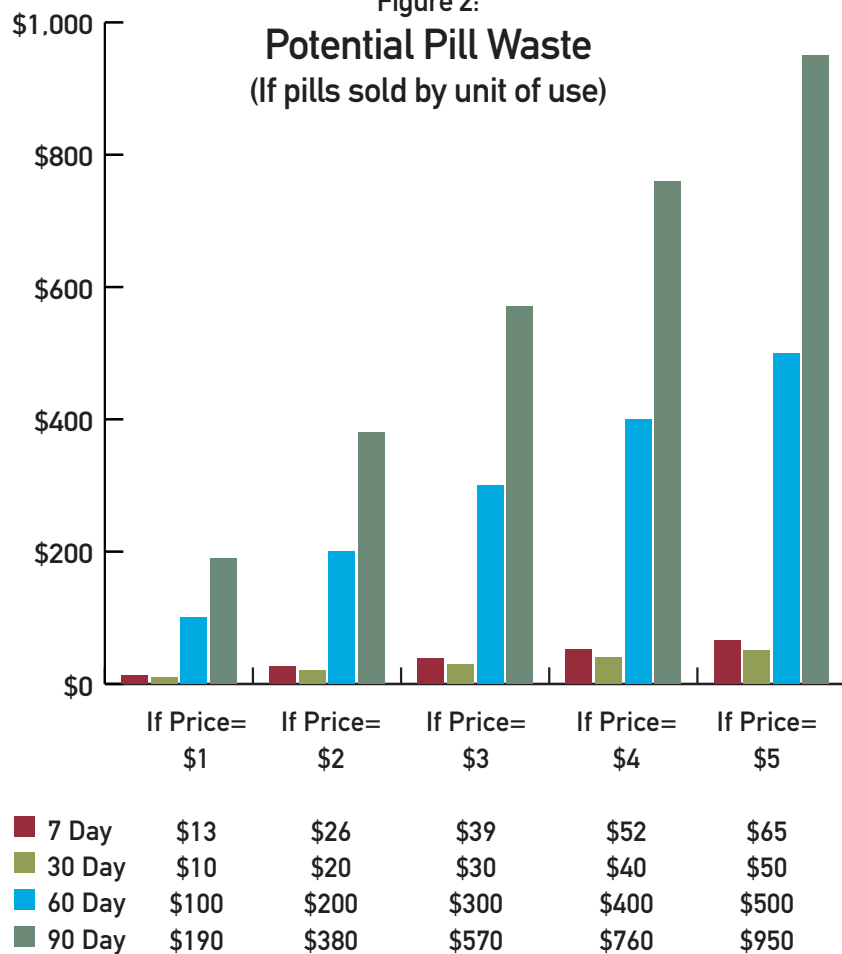
Canada, the majority of the retail outlets are pharmacy drug stores. Most often these UOU packages are blister packs with predetermined numbers of pills such as 7, 14 or 30 pills, or other quantities.

UOU packages present two distinct problems that add cost to the distribution system. First, if the consumer’s prescription calls for a number of pills that are not available in the blister pack set of pills, the pack must be



Figure 1:
 AN AUTOMATED PILL-DISPENSING SYSTEM SPEEDS FILLING WHILE VERIFYING ACCURACY.

Figure 2:
Potential Pill Waste
(If pills sold by unit of use)



modified to achieve the actual number of prescribed pills. Sometimes the pack is opened, which can lead to errors when the strips of blisters are separated from the original pack and are not fully labeled.

Secondly, the variety of languages in Europe present another complication because the prescription labeling and/or instructions must be in the consumer's native language. Again, this means that blister packs often require re-labeling or repackaging in some way. Given the rising costs of health care, little consumer benefit is obtained by adding costs to the drug distribution system.

The following presents the advantages of P&C over UOU:

1) System Flexibility: Doctors can prescribe any pill quantity for the patient with P&C versus the UOU pre-set blister pack

quantity that may result in pill wastage.

2) Ease of Use: For the patient, P&C provides both child-resistant and non-child-resistant packages which are consumer friendly. Child-resistant blisters in UOU are very difficult to use, especially by elderly or arthritic consumers.

For the pharmacy, robotic systems are now available to fill and label vials accurately and efficiently. The systems (see Fig. 2) dispense tablets and capsules accurately, print labels, record lot numbers and expiration dates, verify all actions and store inventory data.

3) Pill Wastage: When a prescription is written for a quantity of pills other than that available in a pre-packaged blister pack, the pharmacist has two choices:

a) Dispense the pills in the amount

prescribed by cutting or otherwise manipulating the blister pack. The extra pills should be disposed to avoid potential liability issues of dispensing them as part of another prescription.

b) Give the customer the extra pills, which also creates waste and potential liability.

Although exact statistics are not available, a leading drug store association estimates that approximately 80% of prescriptions are written for pill quantities of 5, 10, 20, 30, 40, 50, 60 and 90, with 20% of the prescriptions spread out over other quantities. Pre-packaging blister packs in so many stocking units (SKUs) is not manageable.

This simple example quantifies the UOU waste in dollars: Take 1000 pills, written as prescriptions from various doctors and stipulate that the prescriptions written for these pills call for 3 pills/day. Assume the pills are only available in packs containing 7, or 30, or 60, or 90 pills, i.e., a single stock keeping unit (SKU) for each size blister pack. The wasted dollars are shown in Figure 2 and grow as the drug cost increases. For \$1 pills packaged in the 30-day packs, the waste is \$10/1000 pills (the pharmacist can make 11 prescriptions of 90 pills each, with 10 pills as waste). For \$5 pills packaged in the 90-day packs, the waste is \$950/1,000 pills (the pharmacist can make 3 prescriptions of 270 pills each, with 190 pills as waste).

Even if the blister packs were available in all four counts, the pharmacist would need to calculate the best combination to dispense, but there would still be waste and added costs. Expanding this example to thousands of pills at many more unit dosages than four, and across pill costs ranging from pennies to \$100/pill or more, billions of dollars in cost would be added to the distribution system.

4) Packaging and Handling Costs:

P&C vials cost less than 10¢ per package to the pharmacist, on average. Blister packs will cost anywhere from 10¢ to over \$1.00, depending on graphics and package construction. Handling costs could be twice as much for both the distributors and the retail outlets for shipping, receiving and stocking the many sizes of UOU blister packs versus the single size bulk-pack containers used in P&C.

5) Space Requirements: Again, due to the sheer number of UOU pre-set packages required, compared to the number of bulk-pack containers needed in P&C, storage and space requirements become an issue. Although the distributor may store pills for the retail outlet, this added cost is passed on to the entire supply chain and to the consumer.

6) Ordering/Invoicing/Paying: Each size UOU package is a separate SKU line item on orders and invoices. UOU is estimated to have more than three times the number of SKUs than P&C, requiring additional labor to process the orders and invoices, which also increases the possibility for errors.

7) Tracking Lot Numbers and Expiration Dates: P&C, especially when used with a robotic system, requires only one entry to identify a batch and/or expiration date. UOU requires more labor and a complex storage and stock rotation.

8) Environmental Issues: The P&C system utilizes bottles and vials that are recyclable. UOU packs generally contain a mixture of materials including plastic, paper and/or metals which are difficult to separate and recycle. Thus, the packs are typically disposed of in landfills or burned in waste-to-energy facilities.

9) Patient Safety: Many of the above points touch on the very important issue of patient safety. The bottom line is that there is a lower level of patient safety in the UOU system than in the P&C system. This arises from a number of factors, including the tendency in UOU systems for staff to break open packs and dispense strips of blisters with totally inadequate labeling. Errors are also introduced in the handling of the packs themselves. With a myriad of packs of different strengths and quantities on the shelf, it is easy for pharmacy staff to pick the wrong pack and dispense it to a patient. One major UK pharmacy chain has traced the predominant source of these errors to erroneous stocking of the packs on the shelves in the first place.

Throughout this article, we have used

UOU and blister packs as synonymous and of course, there are also UOU bottles. UOU bottles represent the same pill waste and handling issues. For example, if a UOU bottle is 30 pills and the prescription is for 20 pills, 10 pills are waste and re-labeling, handling and storage, etc., are all similar issues as the blister packs.

The most commonly advanced arguments for UOU are generally qualitative and include:

1) Regulatory Compliance: The primary driving force behind adoption of the UOU system in Europe has been the EU health policy requirement to provide a patient package insert (PPI) to each patient with his/her prescription. The PPI is the manufacturer's comprehensive technical information sheet regarding the drug and is similar to the package insert (PI) that is required in the U.S. to be provided to the pharmacist, but not the patient. U.S. pharmacies provide drug information to patients in more usable, less technical form through pharmacy printed monographs. In order to comply with EU health policy, manufacturers are required to insert PPIs into the UOU packs, and this has driven European pharmacies into the UOU system. However, when UOU packs are opened and blisters dispensed separately, there is only one PPI available and thus not all patients get the required PPIs.

2) Patient Compliance: Because blisters show the pills in a more visual format, it is argued that people can see the pills and more easily determine whether they have taken them properly. While this may be true when the prescription is for a small number of pills, the practical advantage is lost for larger sized prescriptions, in which the consumer would need to count the number of pills.

3) Brand and Image

The blister allows a pharmaceutical company to establish or reinforce image and brand. No argument on this, but how does this benefit the rest of the supply chain?

Blister packs typically have a smaller la-

bel area than P&C containers, unless the blister contains a large number of pills or the pills are a very large size. Also, in order to include specific customer information, a UOU may require a secondary package or the consumer's specific information may obscure the manufacturer's original label information.

4) Security of the Package

It is argued that the blister packs are more secure because the package is not opened in the supply chain; only the consumer opens the blister pack. Unfortunately, this argument is false, as security breaches have occurred by counterfeiters copying the entire package, rather than just substituting the actual pills. While the manufacturer may be able to demonstrate that the package is a fraud, it is after the fact, which is no benefit to the consumer.

5) Labor Savings

UOU saves the labor by avoiding the pouring and counting of pills. This is certainly not true if the pharmacy uses an automated filling system. Pharmacies that do not have robotics almost always have an automated counting machine and the extra labor required to handle UOU packs balances the labor required to use an automated counting machine.

This comparison of the P&C system to the UOU system highlights the advantages of P&C. In our view, it is no coincidence that the U.S. health care industry which is been driven by private enterprise, has evolved to a more economic supply chain in P&C, while the more government-regulated European economy has migrated to the UOU system. In summary, each system has utility. But, as the debate around the world continues, economics and ergonomics should be the principal driver, rather than unsupported emotional claims.

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