Are newer medications better than older ones?

Many highly effective medications have been introduced during the past couple of decades. These have improved the care of patients with many diseases, including cardiovascular disease, asthma, gastrointestinal diseases and rheumatoid arthritis. Good progress has also been made in treatment of many cancers. Despite these advances, caution is urged when you and your physician consider a recently approved medication.

What proportion of new medications represents major breakthroughs?
Every year, the FDA approves approximately 20 to 25 new unique medications (molecular entities) for marketing, of which no more than four to five represent major advances for conditions with no good treatment choices. The remaining new medications offer marginal improvements or are combinations of already marketed products.

In the highly profitable areas involving medications for treatment of high blood pressure, high cholesterol and osteoporosis, there is intense competition. Many of the newer medications for these conditions are very similar to the successful medications already on the market. One could question whether these agents offer any important advantages to patient care. On the other hand, even a small share of a large market can be very profitable for the manufacturers. These agents are often referred to as “me-too” drugs because they are so similar.

Are newly developed medications better than older established ones?
There is no regulation requiring new medications to be better than older ones before they are approved by the FDA. As pointed out in the previous chapter, there is a shortage of good and fair head-to-head testing of new medications in comparison to proven existing drugs on the market. Thus, it can be difficult for doctors and health plans to determine if the newer (and typically much more expensive) medications add value.

As noted earlier, it is much easier to compare medications that are indicated for alleviation of symptoms. You and your clinician have the option of conducting your own experiment by trying the new medication for some time and then concluding whether it represents a step forward. Be wary of all marketing claims aimed at convincing you about the wonders of a new medication.
For preventive treatment, it is more difficult to determine (in the absence of
good clinical trial evidence) whether the new drug is superior, equal or inferior
to established medications. Similar effects on surrogate treatment outcomes
do not tell us whether the new medication is better in preventing disease
complications or prolonging life. Answers to these questions require large,
costly trials that may last four to five years.

Another thing to think about when weighing the pros and cons of new
and established drugs is that older drugs have been on the market for many
years. This market experience is very important from a safety perspective.
For more than half of all new medications, a previously unrecognized serious
adverse effect is detected during the first years of marketing. In some cases,
this results in removal from the market or the addition of black box warnings
to medication labeling. There are always potential risks in taking a new
medication. For this reason, many physicians and health plans prefer to wait
a few years before they recommend a new drug, especially if there are good
treatment alternatives available.
**What is needed?**

Medicine and the public health would be much better served if newer medications offered clear advantages by being more effective, safer and/or less expensive than older ones. Unfortunately, there is no such regulatory requirement. Instead, the market is flooded with “me-too” medications. Through skillful promotion to doctors and consumers, these agents do well in the marketplace, which is a sad statement of fact.

**Key messages**

- Only a small number of new medications represent real breakthroughs.
- For medications that bring symptom relief, it is easier to determine whether “new is better.”
- For preventive treatment, caution is advised, since better-documented, older medications often trump newer, more expensive ones.
- It is often advisable to wait a couple of years until there is good safety documentation before taking a newly marketed medication.