

## Pharmaceuticals for Elders: Why Innovation Matters

by Albert Wertheimer

The current policy debate over drug-benefit reform and improved access to needed medicines for elders has generated considerable confusion and many misperceptions regarding the nature and value of incremental pharmaceutical innovation. Yet it is clear that most clinically important drugs have been developed as a result of an evolutionary process involving multiple small, successive improvements within a pharmacological class.

The cumulative benefits of these new medicines are striking, because having access to a broad class of drugs enables physicians to treat with greater precision the individual needs of diverse patients. These improvements are especially important for optimal treatment of older patients, because age-related physiological changes and individual differences may produce markedly diverse responses to medications in older adults.

Some critics have suggested that since most new drugs do not represent breakthrough innovations, their value is questionable. But incremental pharmaceutical

improvements provide several important benefits to patients:

- Fewer side effects.
- Improved safety and effectiveness.
- Greater ease of use, facilitating compliance with prescribed therapeutic regimens.
- Product alternatives that permit treatments to be better tailored to individual patient needs.

The availability of multiple similar agents in a drug class is of particular value to elders. Variation in response to medications is common among older adults, resulting in part from individual differences related to coexisting medical conditions, organ function, frailty, cognitive ability and capacity to perform activities of daily living. As people age, the range of individual physical and medical differences increases. Compared with younger patients, elders are more likely to experience atypical, enhanced or adverse drug effects.

Therapeutic options within classes of medications offer elders and their physicians choices among similar agents with somewhat different pharmacological properties and side effects. Even choices

of form—such as tablets, capsules or liquids—can benefit certain patients, such as those with stroke or Parkinson's disease, who may have difficulty chewing, swallowing, or measuring and pouring liquids.

Controlled-release formulations, which have a long duration of action and are taken only once or twice daily, can reduce side effects while maintaining effectiveness; the resulting simplified regimen facilitates patients' adherence to medication schedules. Such forms also allow greater independence for older residents in long-term care facilities, who are often extremely frail and predisposed to adverse drug effects.

Over the past decade, growing numbers of older Americans have benefited enormously from incremental improvements in medicines used to treat a variety of chronic diseases. Following are a few examples:

### **Cardiovascular Conditions.**

Ongoing innovation has led to advanced dosage forms and delivery systems for existing cardiovascular agents that can provide

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considerable therapeutic advantage—especially for older patients. Controlled-release dosage forms can improve the effectiveness and safety of medications, as well as simplify dosage regimens. For treating high blood pressure, for example, once-daily dosing with the new forms provides extended coverage and protects against the risk of sudden death, heart attack or stroke caused by an abrupt rise in blood pressure in the early morning.

Similarly, the use of tissue plasminogen activator (t-PA) to treat stroke patients demonstrates how ongoing innovation can lead to an important new use of a medication designed for another purpose. Originally approved for dissolving blood clots in heart attack patients, t-PA was subsequently found to dissolve blood clots in the brain, restore blood flow and limit permanent brain damage.

**Urinary Incontinence.** Incontinence is a significant cause of disability among elders and is often a primary cause of institutionalization, due to the burden of care the disease creates. Continued research into treatments for incontinence has resulted in a once-daily, controlled-release formulation of oxybutynin that maintains consistent release of medication over 24 hours, thereby averting the peaks in blood levels seen with the immediate-release form of this drug.

**Diabetes.** Diabetes affects more than 18 percent of older Americans. Ongoing innovation has led to an array of insulin products ranging in their time of onset and duration of action. Premixed insulins reduce the risk of hypoglycemia because they are more convenient, improve compliance and dosage accuracy, and may help older or impaired patients who have difficulty preparing an injection from two vials. Insulin nasal sprays, currently in development, will aid individuals who are squeamish about injections, reduce infections and accidental needle sticks, and reduce cost and disposal concerns by eliminating the need for needles and syringes. Sulfonylurea agents, another mainstay of diabetes treatment, differ widely in potency and dosage, duration of action, side effects and potential for interaction with other drugs, enabling physicians to match effective treatments with older patients' overall health and lifestyle.

**Chronic Obstructive Pulmonary Disease.** Drugs that expand the airways are the mainstay of treatment of chronic obstructive pulmonary disease, the fourth leading cause of death in the United States. These agents are used in inhaled, metered-dose formulations and differ in potency, selectivity of action in the lungs, duration of action and side effects. The short-acting agent albuterol is now being manufactured in its

purier, single-isomer form, which appears to be more potent. Since it requires a lower dose to achieve its therapeutic effect, patients experience fewer side effects.

## POLICY IMPLICATIONS

These examples underscore the importance of incremental pharmaceutical innovation, as well as the need for policies ensuring patients' access to choices among drug treatments. Policies that foster the availability of unique, incremental innovations along with breakthrough drug discoveries can have important implications for treatment outcomes, patients' quality of life, cost containment, and ongoing research investment in newer and more effective medicines. The availability of a wide range of choices is especially important for older patients, who have the greatest need for individualized care and are most at risk for compromised outcomes if drug choices are limited. ■

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