INNOVATION IN THE PHARMACEUTICAL INDUSTRY

What is innovation?
The Conference Board of Canada defines innovation as the process through which economic and social value is extracted from knowledge through the generation, development, and implementation of ideas to produce new or improved strategies, capabilities, products, services, or processes.

The stories of how new drug development takes place can be fascinating to learn. Occasionally drug discovery can happen through serendipity (chance or luck), but most new pharmaceutical innovation occurs as a result of years of research and lots of hard work. In the past, most drug discoveries were made by isolating and distinguishing the active ingredients in traditional medicines or plants. For instance, once it was understood that the antibiotic penicillin came from a mold, the widespread screening of other molds, microbes and microbial byproducts took off in an attempt to find the next significant antibiotic. In this case, one innovation provided a clue as to where to search for more antibiotics. Learn more about Canadian innovations in pharmaceutical research and development in the Canadian Innovations in Pharmaceuticals timeline.

What is a ‘blockbuster’ drug?
You may have heard the term ‘blockbuster drug’ at some point. When we hear the term blockbuster it is usually in reference to movies that are very popular and make lots of money at the box office. When this term is used to describe pharmaceutical products, it means a breakthrough or revolutionary innovation – a drug that is a totally new which fulfills a therapeutic need that has never before been achieved or acts in the body in a novel or unique way. Years of research can go into identifying new compounds or molecules that can be developed into a blockbuster drug. Often a blockbuster drug comes with financial rewards from sales of the product and sometimes notoriety for the discovery, like the discovery of insulin, but this is not always guaranteed for pharmaceutical research and development. Examples of early blockbuster pharmaceutical innovations include the discovery of Aspirin, insulin, penicillin, and calcitonin. More recent blockbuster innovations include the first birth control pills in 1960, the antiviral zidovudine (AZT), which was a major breakthrough in the treatment of HIV and AIDS in 1987 and the introduction of the first anti-cancer vaccine against human papilloma virus (HPV) in 2006. It is estimated there are about 125 blockbuster drugs on the market currently.

What is incremental innovation?
In reality, there are not nearly as many blockbuster or breakthrough innovations as we would like to believe. Although we think of our mobile phones, for instance, as new and innovative, they are really part of a long innovation continuum that began with the ‘blockbuster’ innovation, the first telephone, which was invented by Alexander Graham Bell (see Figure 1: Alexander Graham Bell on the telephone in New York (calling Chicago), 1892. Source: http://en.wikipedia.org/wiki/File:Ale xander_Graham_Telephone_in_N ewyork.jpg Wikimedia Commons.)
Even if we considered the first cellular phone as a blockbuster innovation, there is a huge difference in the first clunky cell phones from the 1980s compared to the cell phones of today - phones that let us make a phone call, text, access the internet and even take pictures and video clips to share with anyone, anywhere in the world. Although we consider these changes and improvements as innovations, and they occur as the result of applications of research and development, because they are small changes or improvements on an existing product, they are called *incremental innovations* (see Figure 2).

**Incremental Innovation in Pharmaceutical Research & Development**

Incremental innovation is the primary method that new products or processes are discovered and applied to medical treatments. Most breakthrough drug innovations, new drug combinations and novel medical procedures are generally the result of incremental innovations. Scientists work within an existing global knowledge base, learn from others by reading medical research literature, and respond to what is happening in many areas of science and technology. Often new technologies impact on innovation. Advances in genomics and proteomics have provided the ability to sequence proteins and understand small structural differences in proteins which has offered biochemists new methods to search for potential drug candidates. Genetic engineering has impacted how vaccines can now be created. Nanotechnology holds the promise of building nanostructures that can carry bioactive compounds to specific *target tissues* in the body and then release them, which may reinvent the way we use some of our existing medicines.

**Small Innovations Add Up**

In the pharmaceutical industry, incremental innovation typically results in the generation of *classes of drugs* - groups of drugs that have similar chemical composition and treat similar medical conditions (e.g., *penicillins*, *macrolide* antibiotics, cholesterol-lowering *statins*, and anti-inflammatory *corticosteroids*). Pharmaceutical technology can also be incrementally improved, as exemplified by changes made in the design and function of glucose pumps; devices used for the administration of insulin in the treatment of diabetes (see Figures 3 and 4).

Why would we need to have multiple drugs that do the same thing? Just like the fit of shoes,
one size does not fit all when it comes to medications. Different variations of drugs within a class of drugs can offer doctors more options for prescribing the most effective medicine for patients – options for patients who have undesirable side effects and to provide different routes of administration of the drug, such as a pill versus oral liquid or injectable formulation. For instance, in the treatment of schizophrenia there are newer long-acting injectable antipsychotic medications available which can help to ensure that patients who may be incapable of remembering to take daily pills have accurate, consistent and timely dosing of their medication.

In Canada, each new incremental drug innovation must go through the same clinical trial, regulatory review and licensing process as ‘blockbuster drugs’ because every developed drug product must be ‘chemically’ different and demonstrate that it offers an improvement over an existing product. For doctors and their patients, the overall effect of incremental innovation can mean improvements in the safety, efficacy, selection and uses of a drug within a class of drugs. In just 10 years, between 1996 and 2006, incremental innovation resulted in amazing differences in the drug therapy regimes for human immunodeficiency virus (HIV) (see Figures 5 and 6).

The Business Side of Innovation
From a business perspective, incremental innovation can expand the product line a company has to offer, which can increase profits. For research pharmaceutical companies (companies involved in scientific research efforts leading to the development of new drugs) a portion of company profits always goes back into research towards making new drugs. A variety of similar products on the market creates competition among drug manufactures, which can lead to lower costs for drug retailers and consumers. Generic drugs are drug products which are copies of brand/reference listed drug products that can be manufactured once the original product patent (a grant of exclusive protection for an invention) on a drug expires. Generic drug manufactures make their own version of the branded drug (See Figure 7) that offers similar dosage form, strength, route of administration, quality and performance characteristics, and intended use as the original patented drug. Generic companies create competition in the pharmaceutical marketplace and more choice and pricing options for drug wholesalers, retailers and consumers, but they are not involved in the research and development of new medicines.

Figure 5: 1996 HIV Therapy: complex regimens with high pill counts. Image source: Drug Information Association, used with permission.

Figure 6: 2006 HIV Therapy, one pill once daily. Image source: Drug Information Association, used with permission.

Figure 7: Generic Ibuprofen. Image source: http://en.wikipedia.org/wiki/File:Bottle_of_Ibuprofen_tablets_with_cap_removed_and_tablets_in_front.jpg Wikimedia Commons.
References

This Innovation page of the Conference Board of Canada provides a definition of innovation, the indicators of performance for innovation, and Canada’s global position with respect to innovation.

Encyclopedia Britannica. 7 Drugs that Changed the World. (Accessed February 19, 2014)
This student-friendly page outlines seven of the world’s most life-changing pharmaceuticals.

This is an International Policy Network working paper on intellectual property, innovation and health. It outlines the role and impacts of incremental innovation in pharmaceutical research and development.

This is a fact sheet about long-acting injectable antipsychotic medications, including options, benefits and other medical considerations.