Why You Should Care About Regulatory Science

When someone uses the word "science," you might think of chemistry, biology, or physics, to name just a few fields.

You probably wouldn't think "regulatory science."

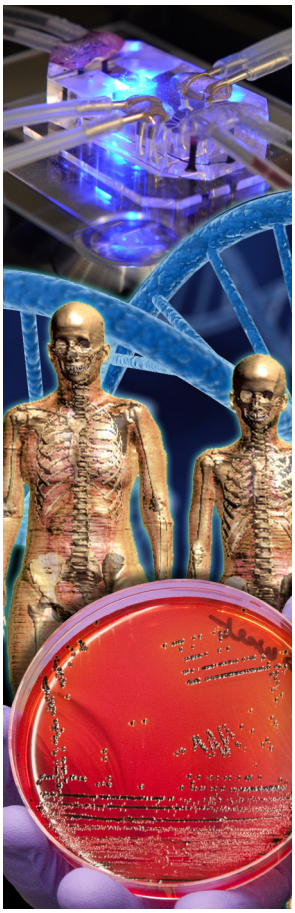
But it's a field that has a big impact on the daily life of the average consumer. "The breadth and scope of FDA's regulatory oversight is extraordinary, touching the lives of every American, through the food we eat, the medicines we take, and the medical devices we use," says FDA Commissioner Margaret A. Hamburg, M.D.

That oversight is based on the sound science, called regulatory science, that is the foundation of FDA's day-to-day decisions. Scientists throughout the agency research the development of new ways to evaluate FDA-regulated products.

"As new discoveries yield increasingly complex products, the agency must be able to make science-based decisions that result in sound regulatory policy," says Hamburg.

And there's a need for speed.

"There's a gap between research and discovery—which is ongoing and very vibrant—and the actual delivery of products to the market and to those who use them," says FDA's Vicki Seyfert-Margolis, Ph.D, senior advisor for science innovation and policy. "So this is an area that we think is critical for making that link between discovery and the actual product on the market."



The Impact on You

Regulatory science is the science of developing new tools, standards and approaches to assess the safety, effectiveness, quality and performance of FDA-regulated products. These Consumer Updates explore how regulatory science will affect your daily life by:

- Personalizing Medicine
- Reducing Drug Side Effects
- Embracing New Technologies
- Keeping Food Safe

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Focus areas

In August 2011, FDA released its "Strategic Plan for Regulatory Science," an initiative that identifies eight priority areas essential to the continued success of FDA's public health and regulatory mission. The plan is wide-ranging, with its target areas including personalized medicine, food safety and medical countermeasures to protect against threats to U.S. health and security.

- Personalized medicine involves the development of treatments that are tailored to an individual patient or a group that shares certain genetic characteristics.

"Medical science is now capable of creating treatments that are guided by the patient's unique genetic information," says Alberto Gutierrez, Ph.D., director of the Office of In Vitro Diagnostic Device Evaluation and Safety in FDA's Center for Devices and Radiological Health. In June 2011, FDA approved a novel genetic test to determine if breast cancer patients are candidates for Herceptin drug treatment.

"These treatments can be

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specifically tailored to provide individuals with maximum health benefits while posing the minimum of risks," says Gutierrez. "We're approaching an era when 'one size fits all' medications will no longer be the doctor's only option."

- FDA's long-range goal for food safety is to prevent food safety problems from happening in the first place. But the agency also needs the tools to contain problems if they do occur and to understand how they occur so they can be prevented in the future.

"Food safety can be affected at many points along the farm-to-table chain, and our goal is to establish preventive controls at each step to minimize hazards," says Michael Taylor, J.D., the deputy FDA commissioner for foods. "But success requires the most advanced science and technology to know what preventive controls are needed, to detect problems when they happen and to minimize illnesses when outbreaks occur."

The need for state-of-the-art know-how was shown in 2010, when an oil rig explosion dumped more than 200 million gallons of crude oil into the heavily fished waters of the Gulf of Mexico. When the crisis began, the chemical test to confirm that seafood was free from harmful oil residues took about a week to run—too long for the large number of samples that had to be analyzed.

To solve this problem FDA scientists, working with state partners, developed a new testing procedure that could detect oil-based contaminants in seafood in just 24 hours. The time saved by using the new test enabled FDA and state authorities to safely reopen the Gulf for fishing weeks sooner than would have been possible using the existing test. This meant seafood harvesters could go back to work sooner and consumers could again safely enjoy seafood from the Gulf.

- Infectious diseases—including those that could occur from hostile attempts to harm Americans—can take many forms and present FDA with serious challenges. FDA's Center for Biologics Evaluation and Research has been studying potential hazards that range from smallpox and influenza epidemics to anthrax attacks and radiation poisoning.

FDA is tackling these threats through research and collaboration focused on medical countermeasures. For example, the agency has worked with the Centers for Disease Control and Prevention and industry to help manufacturers develop tests to prevent transfusions of blood and transplantation of organs infected by the West Nile virus. FDA's work was critical in facilitating rapid development and deployment of these tests. Other major objectives of FDA's regulatory science research include:

1. The development of technologies to accelerate the large-scale manufacture of new influenza vaccines.
2. Creation and evaluation of rapid testing methods for the detection of infectious microorganisms in such biological products as blood and tissue.
3. Finding new methods to improve the shelf-life and stability of products that have to be warehoused for use in an emergency.
4. Formulating new ways, such as needle-free systems, for more rapid use and self-administration of drugs.

Other priority areas include improving the design of clinical trials and manufacturing processes.

Advances in these areas will bring more innovative medical products to the market to help people with chronic and life-threatening diseases, says Seyfert-Margolis. "I think that's where the consumer would really appreciate or feel the investments that are made in this area." FDA

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