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Experimenting with the Consumer

Marshall S. Shapo
Praeger Publishers
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Reviewed by BRIAN J. PANISH

Human experimentation on a massive, unsuspecting population: Sound like a plot from a science fiction novel or a description from the Nuremberg trials of Nazi war criminals?

Not so, says Northwestern University School of Law Professor Marshall Shapo in his book *Experimenting with the Consumer: The Mass Testing of Risky Products on the American Public.* We are all human guinea pigs unwittingly subjected to experimentation by manufacturers, scientists, and regulators, he writes. For us, there are no carefully controlled procedures or people in white lab coats—and there is certainly no informed consent. Instead, risky products are disseminated prematurely for consumers' use, so that manufacturers can obtain real-world product-risk data.

Of course, deaths result when the risks of certain products—such as Vioxx and fen-phen—are found to greatly outweigh any benefits. But to manufacturers, those deaths represent a "sacrifice . . . along the way to innovation," Shapo writes. And these are not obscure products that only a few unsuspecting people use. They are drugs and devices that the mass media promote as highly desirable for certain segments of our population, and they have taken the market by storm.

Experimenting with the Consumer explores the interesting cases of Viagra, breast implants, hormone replacement therapy, and cutting-edge nanoparticles as examples of this mass experimentation. These products and others like them are sometimes developed from accidental discoveries and enter the market on the basis of razor-thin data. Then pharmaceutical companies expose millions of experimental "subjects" to their effects.

With so many people exposed to unknown risks at once, it is difficult to immediately recognize whether a reported problem or cluster of adverse events requires government attention. Manufacturers rally to get their own stable of scientists to dispute any causal relationship between their products and adverse side effects. Predictably, a protracted period of scientific disagreement ensues, which delays any resolution.

For people unwittingly subjected to drug experiments, there are no carefully controlled procedures—and there is certainly no informed consent.

Manufacturers have financial incentives to misrepresent or hide experimental data and other critical information both before and after the FDA approves their products—and this information sometimes remains hidden from the public until it is dragged out of the manufacturers in lawsuits. As a result, science, medicine, the media, politics, and the law all must interact until the risks can be identified, assessed, and, most important, disclosed.

The victim, of course, is the consumer. After a particularly dark period of human history, the Nuremberg Code of 1947 (which serves as the basis for portions of our Code of Federal Regulations and related state statutes) specified that people could serve as subjects for medical experiments only after giving "essential" voluntary consent based on an "understanding and enlightened decision." Sixty-two years later, American consumers are unknowingly participating in experiments without having received sufficient information. Drugs that are released prematurely based on falsified scientific data raise significant ethical issues that all of us must examine carefully.

Shapo is a products liability guru with a special personal interest in science: His father believed his top-secret work for a coppersmith firm during World War II was related to the Manhattan Project. Even though recent lawsuits have revealed much of the information contained in his book, Shapo gives a thorough, detailed, and balanced analysis that provides powerful food for thought. Products liability trial attorneys who represent consumers may well find their next case theme in the pages of this book.

I would recommend *Experimenting with the Consumer* to members of both the plaintiff bar and the public. As Shapo states, we should not be afraid after reading the revelations in this book; rather, we should all be a little more sensible. If we know that we are all experimental subjects, we can take commonsense steps to protect ourselves, such as judging for ourselves what risks to take, spending sufficient time and energy investigating the risks of any new product, and viewing everything with a healthy skepticism. ■

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