

BEHAVIORAL SCIENCE – AN ESSENTIAL INGREDIENT FOR THE INTERFACE OF REGULATORY SCIENCE AND SELF-CARE

R. WILLIAM SOLLER

University of California San Francisco

Consultant for the Pharmaceutical and Health Communications Industries, Houston, Texas

The Food and Drug Administration (FDA) defines regulatory science as ‘the science of developing new tools, standards and approaches to assess the safety, efficacy, quality and performance of FDA-regulated products.’ A. Alan Moghissi is credited with coining the term in the 1970’s in relation to the complex array of issues facing the new government organization called the Environmental Protection Agency. Since then, regulatory science has come to be seen as having interdisciplinary and multidisciplinary components, and is distinguished from regulatory affairs which is construed as an administrative function. At its core, the premise underlying regulatory science pertains to the notion that societal decisions should be made based on the best available science.

FDA’s definition is quite broad, and literally can be applied to all stakeholders in FDA’s decision making who are involved in the safety, efficacy, quality and performance of all products regulated by the agency. This includes pharmacology/toxicology, clinical pharmacology, clinical efficacy and safety outcomes, biostatistics, pharmacoepidemiology, manufacturing, food science and safety, biotechnology, and engineering devices and diagnostics, among other disciplines.

In terms of self-care, regulatory science can also be considered as a broad overarching concept. So too, self-care can be appropriately defined broadly in the context of both patients and consumers. For example, self-care encompasses patients with diabetes working daily through a medication action plan in the interim period between visits. It also includes consumers self-selecting a treatment for overactive bladder, prevention of gingivitis, headache and other common conditions. Whether prescription or OTC, the disciplines comprising regulatory science are the same. In essence, safety is safety, efficacy is efficacy, and quality is quality. For drug and safety issues for example, FDA applies a risk management approach with a common multidisciplinary theme that draws as needed on those with expertise in animal toxicology, absorption/distribution/metabolism/excretion, bioavailability, formulations, manufacturing controls, clinical care of patients, drug labeling, drug safety and surveillance, among other domains.

Of particular note pertaining to the regulatory science associated with nonprescription medicines is the emphasis on demonstrating successful end-user application of understandable labeling in the self-selection and deselection of nonprescription products at the point of sale, as well as under conditions of actual use. To achieve this, regulatory science was extended in the U.S. in the 1990's to supporting societal decisions about Rx to OTC switch, thus creating a niche discipline defined by scientific expertise in self-selection, label comprehension and actual use studies.

Yet, over the years the percentage of patients who do not read the nonprescription drug label remains high*. On the prescription side of regulatory science, the scene appears the same. A medication education gap exists in the US, and likely elsewhere internationally, in terms of the extent to which physicians and pharmacists fully counsel patients on essential elements of safe drug use. There is also substantial concern about whether patients responsibly undertake self-care with prescription medicines by self-educating before they self-medicate with prescription medicines (i.e., during the months between physician visits). Thus, quite a lot of regulatory science has been applied to the concept of predicting safe product use during marketing, yet there is relatively little to show for it. This is not an inconsequential problem. The product label is the fundamental interface that FDA has established between the product it approves and the consumer who buys the product.

It is clear that FDA expects that patients should read the OTC label before use, and physicians and other counseling practitioners should specifically inform patients about essential drug information before use. For OTCs, FDA and companies at FDA's recommendation expend substantial resources to create an understandable label with high utility. For prescription medicines, FDA revised the Full Prescribing Information in 2006 to create an initial section on most essential information, a table of contents, and 17 sections of detailed drug information. The last of these sections ('Section 17') is entitled patient counseling. It is written in the grammatical imperative, specifically directing the practitioner that 'the patient shall be informed that... [complete directive with key safety concern]...'. Most US practitioners know about Medication Guides designed for products with very high risks of serious side effects and also written in the grammatical imperative. Yet, 'Med Guides' cover only a small portion of all prescription medicines. In my experience working with practitioners (physicians and pharmacists), many do not know what 'Section 17' is and do not know that FDA specifically directs them to use the information in Section 17 when counseling patients about medicines.

So, how is it that we have this chasm between regulators' expectations of the label and use of the label in practice? I posit that the solution is ultimately in the domain of behavioral science, which typically has a minor role in understanding the actual use of labeling by consumers, patients and practitioners. Behavioral science is not routinely brought into societal decisions about product availability from the standpoint of how to change consumer, patient and practitioner behavior in the use of the label after market approval. Certainly, behavioral science has been applied in the areas of smoking cessation products, where counseling is based on the stages of change.

* See Soller RW and Shaheen C (2011), for a review and primary data on the Rx and OTC medication education gap in the United States. *SelfCare*.2(3):66-75.

Human factor studies are used as a basis for approval of certain devices. And, most health professional schools in the U.S. spend some time teaching basic principles of counseling, usually by teachers with clinical credentials and limited social science training in health communications. Yet, we must understand what motivates consumers and patients to read the label and retain it during use for reference in relation to emergent conditions. So too, we must understand what motivates practitioners to counsel patients as expected by the standard of regulatory science espoused by FDA. Without application of such learning, policy makers will not achieve in the large majority of the general population the oft stated goal of educate before you medicate.

I suspect that behavioral science has only begun to scratch the surface of what we need to know about consumer and patient behavior. This should be an area of high interest to all with a stake in improving drug safety. Public and private funding is needed to better understand and refine consumer and patient behavior with medicines, and a greater emphasis on the discipline of behavioral science should be better enveloped within regulatory science.

Correspondence to: editor@selfcarejournal.com