



Profiling Consumer Products – Are you Ready for Regulation

White Paper

Neil Sherwood, PhD, Manager, Tobacco Harm Reduction Research

DrVinceCRO.com

Introduction

Products which originate from the pharmaceutical and tobacco industries are highly regulated to ensure that their psychological and physiological effects are well understood. Following chemical and toxicological characterization, clinical studies provide the final evidential steps on the pathway towards product marketing authorization. Over the years, staff at Dr. Vince Clinical Research (DVCR) have developed world-leading expertise in understanding the rationale for and conduct of many of these pharmaceutical and tobacco studies.

For pharmaceuticals, where the primary motivation for use is to rectify physiological or psychological perturbations, safety and efficacy are the key endpoints of clinical assessment. Human Abuse Liability studies that include exposure to active substances, short-term impact in a controlled setting, comparisons to existing treatments, adverse events and even the potential of a compound to cause non-therapeutic [human abuse potential have all been undertaken at DVCR.](#)

For tobacco products, given the addictive nature of nicotine, the [FDA Center for Tobacco Products \(CTP\)](#) regulatory requirement for manufacturers is to provide an extended safety assessment which considers not only risk to the individual but to society in general.

[The DVCR Tobacco Harm Reduction Team's](#) core competencies include the conduct of studies evaluating nicotine exposure, biomarkers of exposure and harm, adverse event and abuse liability.

Emerging Consumer Products

More recently, the consumer marketplace has seen a proliferation of consumer products incorporating culturally derived or synthetic compounds with psychological and/or physiological effects (e.g., caffeine, taurine, kratom, cannabidiol). These products are primarily targeted at the general population and are positioned as supporting or enhancing wellbeing. However, the motivations for and consequences of their use are not well characterized, due in part to the absence of clear pathological drivers (i.e., illness, addiction) and the lack of a formal regulatory framework for safety assessment and claim validation.

Nevertheless, one approach to understanding consumer behavior is to recognize that product's appeal to an individual and the satisfaction derived from its use together

provide sufficient dimensional space to describe and understand consumer choices and outcomes. Particularly because these dimensions reflect the well-characterized operation of normal, everyday motivated behavior (McDougall 1922; Rolls 2016). This conceptual focus places motivation for products containing these compounds within the same theoretical space occupied by other everyday consumer goods, from magazines to cars and from donuts to vacations, as they contribute to Quality of Life (QoL), often used interchangeably with wellbeing.

Quality of Life

Product appeal influences appetitive behavior (e.g., searching for a particular food) through incentives such as sensory cues (sight and smell), anticipation and memory after at least the first experience of product use. Meanwhile, product satisfaction reinforces consummatory behavior (e.g., eating the food) through properties such as satiation or intoxication. For the individual, internal physiological or psychological signals (e.g., hunger, boredom or "fear of missing out" FOMO) are perceived as "wanting" and motivate appetitive behavior. Subsequently, the internal signals that follow consummatory behavior (e.g., pleasure, relief) are perceived as "liking" (Berridge 2009). Most importantly, no additional pathological drivers (i.e., illness or addiction) are required to explain such everyday motivated behavior.

In a seminal paper, Müller and Schumann (2011) further delineated the appeal and satisfaction derived from the non-addictive use of products under eight categories:

1. Improved social interaction
2. Facilitated sexual behavior
3. Improved cognitive performance and countering fatigue
4. Facilitated recovery from and coping with psychological stress
5. Self-medication for untreated mental and physical problems
6. Sensory curiosity – expanded perception horizon
7. Euphoria, hedonia, and "high"
8. Improved physical appearance and attractiveness.

While the breadth of these categories captures the universe of motivations, not all compounds exhibit activity in every category, but these categories are all linked in that they appear to contribute to improved Quality of Life for the user.



Behavioral Toxicity

Of course, it is possible that there may also be negative effects from the use of everyday consumer products with psychological or physiological effects on other important activities of daily life (e.g., memory, reaction time). This has been defined as behavioral toxicity (Ramaekers 1998). Moreover, if the use of these products becomes uncontrolled, then harm may result to the user and to others. Such a pathological process underlies, and is the short definition of, abuse liability and subsequent addiction.

There is a growing recognition that behavioral toxicity can be troublesome to both the individual and society, so attempts to quantify such effects have increased. For example, while a comprehensive examination of the effects of medicines on these domains has not generally been required for safety registration, the U.S. FDA has now issued explicit guidance on the need to evaluate vehicle driving impairment if evidence of behavioral toxicity accumulates in earlier phases of drug development (U.S. FDA 2017a). Similarly, environmental protection agencies have previously shown interest in using measures of behavioral toxicity to examine possible neurotoxic effects of environmental pollutants (U.S. National Committee for the International Union of Psychological Science 1990).

The Measurement Landscape

The activities of daily life which influence quality of life and behavioral toxicity cover a multitude of divergent behaviors but may be conveniently captured under the following domains, with examples of related measurable processes in parentheses:

- Biological parameters (e.g., brain imaging, receptor function, self-administration, tolerance) which examine changes to brain structure and function.
- Cognitive parameters (e.g., alertness, concentration, memory) examining skill execution.
- Developmental parameters (e.g., learning, task acquisition, gateway effects) examining the ability to acquire and act upon information.
- Social and personality parameters (e.g., social interaction, emotional lability) which examine the resilience of internal interactions with self and external interactions with others.
- Mental and physical health parameters (e.g., stress resilience, sleep quality, dependence) which examine perturbations to normal function which may lie on the path to illness.

Often, these parameters operate in combination during higher-level activities such as car driving, skilled working, social engagements and hobbies.

DVCR has built significant experience and capabilities to profile consumer experience of product use in controlled clinical settings. We can measure subjective consumer reported outcomes such as appeal and satisfaction, through objective tests of cognitive function and emotional lability such as memory and stress, up to clinical laboratory measures of pain intensity and sleep quality.



Summary

In the absence of an associated technical/legal product standard such as “Safe and Effective” (pharmaceuticals) or “Appropriate for the Protection of the Public Health” (tobacco), consumer product manufacturers may wish to consider what high-level acceptance criteria can be employed to effectively characterize their consumer products and quantify any potential negative impacts on health beyond basic toxicological screening.

As the number of consumer products containing popular or cultural compounds with psychological and physiological effects increases, the assessment of (QOL) and behavioral toxicity may be an appropriate system under which to understand the positive and negative impacts of product use and to satisfy potential future regulatory requirements.

References

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About Dr. Vince Clinical Research

[Dr. Vince Clinical Research \(DVCR\)](#) is a full-service contract research organization (CRO) specializing in early phase trials in both healthy normal volunteers and patient populations across a wide range of trial designs and therapeutic areas such as neuroscience, substance use disorders, dermatology, immunology, cardiometabolic disorders and many others. [CRO services](#) include project management, data management, biostatistics, statistical programming, PK/PD analysis and modeling, clinical and medical monitoring, medical writing as well as site feasibility, management and central laboratory services for Phase I-II multi-site trials with our global network of site partners.

Additionally, DVCR operates one of the most innovative and technologically advanced [clinical pharmacology units](#) in the world with 100 beds for overnight confinement, a cGMP compliant pharmacy as well as luxurious amenities to support diverse study participant recruitment and retention. By leveraging technology and one of the country’s most experienced [leadership teams](#) in early clinical development, DVCR provides Smarter Faster Data® to its biopharmaceutical clients.

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