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Regulating tobacco consumption or nicotine addiction? A review of "The Regulation of E-cigarettes", edited by Lukasz Gruszczynski

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E-cigarettes have had quite some success among consumers. However, we do not yet know the exact nature and extent of the risks they pose. In the absence of definitive scientific guidance, how should regulators respond to this new public health challenge? Should they ban e-cigarettes, or should they allow them on the market? And, if allowed, should they treat them as traditional cigarettes, as medical products, or as *sui generis* products?

"The regulation of e-cigarettes", edited by Lukasz Gruszczynski, is a timely and important review of these and other complex regulatory discussions. The book steps into a debate that has become particularly divisive and controversial. When confronted with scientific uncertainty, public health and environmental regulations often require difficult choices, and can spur intense debates [1-3]. Intense debates can easily become heated in a field like that of tobacco control, which has already experienced decades of well-documented lies by the tobacco industry, as well as attempts to promote misleading "safer" products like light or low-tar cigarettes [4-6]. The book acknowledges this context and does not aim to offer easy solutions. Rather, it seeks to unearth and explore the regulatory challenges posed by e-cigarettes, with a view of reflecting on the experience of this first decade of regulation.

The book offers a multi-faceted and comprehensive analysis of the regulation of e-cigarettes. The first part is devoted to examining the broader overarching questions, with one chapter on the role of e-cigarettes in the history of tobacco control (by Mateusz Zatoński and Allan M. Brandt) and another one reviewing the latest scientific studies on the risks posed by this new product (by Charlie A. Smith, Aleksandra Herbeć, and Lion Shahab). These chapters offer two different perspectives. While the first chapter argues that the history of tobacco control suggests proceeding with caution before embracing any innovation, the second chapter gives e-cigarettes more of a green light, submitting that the limited available scientific evidence already shows that they are "significantly safer" than traditional cigarettes. The two perspectives are not opposed. Rather, they should be read as complementary: even if e-cigarettes could be "significantly safer" than traditional cigarettes (a finding which is not consensual within the scientific community [7, 8]), the history of tobacco control warrants caution and, most importantly, careful regulation.

After the *big* questions, Part II and Part III of the book turn to analysis of the *legal* questions that e-cigarettes pose in international, European, and domestic law. The first chapter (by Lukasz Gruszczynski) reviews the lengthy and mostly unfruitful discussions that took place in the international forum on tobacco control, the WHO Framework Convention on Tobacco Control (WHO FCTC). Subsequent chapters examine the legal questions that could arise in the context of human rights (by Marie Elske C. Gispen and Jacquelyn D. Veraldi) and at the World Trade Organisation (by Marina Foltea and Bryan Mercurio). Two different perspectives are given on the European Union's regulatory framework provided by Article 20 of Directive 2014/40/EU. One chapter (by Anna Pudło and Lukasz Gruszczynski) concludes that the Directive has laid down an imperfect but generally good approach to e-cigarettes, treating them as a *sui generis* product. The other chapter (by Giancarlo A.

Ferro and Costanza Nicolosi) criticises the same Directive for being too prudential. Finally, the last part of the book assesses how some countries have taken diverse and sometimes opposed approaches to the regulation of e-cigarettes (with chapters by: Chuan-Feng Wu, Ching-Fu Lin, and Mao-Wei Lo on Taiwan and China; Patricia I. Kovacevic on the United States; Coral Gartner and Marilyn Bromberg on Australia).

The final picture that is drawn is that of a fragmented regulatory landscape. It is certainly too early to say which experience is the most successful, or which is the optimal model of regulation. Lukasz Gruszczynski seems to favour the European approach, where e-cigarettes have been regulated as a *sui generis* product. Some of the other authors, however, disagree, recommending stricter or looser regulations. One perspective that the book does not explore is that it is possible that there is not an optimal model of regulation at all. The health risks posed by e-cigarettes may have universal or common patterns. However, as we are reminded from the inception of the book, there are hundreds of different types of e-cigarettes, which may pose different health risks. Furthermore, the systemic risks (i.e. the risk that e-cigarettes attract new smokers or that they perpetuate addiction in old smokers) may differ from country to country. In this regard, the experience of the United Kingdom (a country with a strong tradition of tobacco control and very low smoking prevalence) may not be replicable in a country where, for example, smoking is allowed indoors and is still considered socially acceptable. The capacity of a state to enforce its regulations is also, obviously, a critical factor that ought to be taken into account. Bans, for example, can be effective in some countries but totally impractical in others. Social contexts and traditions are known to affect the effectiveness of smoking regulations, and may similarly require different approaches to vaping regulations [9].

By the same token, it is fundamental that any model of regulation of e-cigarettes is aligned with the social goals that are being pursued by policy makers. "The regulation of e-cigarettes" deliberately avoids asking policy questions. However, rather than (only) looking for the optimal model of regulation, policy makers need to ask themselves: What is our endgame? Or better: Are we trying to address the risks posed by the consumption of tobacco, by the consumption of nicotine, or more generally by the repetitive inhalation of any substances? If we decide to focus our efforts on addressing the risks posed by the consumption of tobacco (as the WHO FCTC explicitly does in its Article 3[1]), it may indeed suffice to regulate e-cigarettes as *sui generis* products, as Lukasz Gruszczynski suggests. Conversely, if our focus is on nicotine (*per se* a highly addictive and hazardous substance), stricter regulations could be warranted. Finally, we could decide to consider repetitive inhalation of any substances as a risky activity *per se*, since the defence mechanisms of our respiratory systems cannot effectively expel all toxicants. As a newspaper put it, "evolutionary biologists agree… [that] humans evolved to breathe air" [10]. In this latter case, we should make sure that any regulations on e-cigarettes also apply to smoking of cannabis and of herbal products, before (and not after) cannabis is legalised and these products become mainstream. Science can help policy makers choose their endgame by clarifying the nature and extent of the risks associated with each of these activities (*risk assessment*). But, fundamentally, this is a policy question. Most human activities involve hazards. It is up to policy makers to decide the tolerable levels of risk (*risk management*).

Lastly, and as is acknowledged in the introduction of the book, it is important to remember that any discussion on e-cigarettes is naturally ephemeral. The field is constantly experiencing important scientific and market changes. The wave of "vaping illness" in the United States, for example, recently made headlines, and is prompting several countries to consider a ban on e-cigarettes [11, 12]. As of today, 28 October 2019, we still do not know the cause(s) of the illness. As an article in Nature pointed out, the variables are so numerous that we may never be able to fully understand them [13]. What we know, conversely, is what Patricia I. Kovacevic highlights in her chapter on regulation in the United States and was reaffirmed in a recent article by the New York Times. Because of several difficult political and legal constraints, the Food and Drug Administration (FDA) has left e-cigarettes practically unregulated for almost a decade [14]. Regulating uncertain risks requires difficult choices, but, of all the options, not-regulating a not-risk-free product seems always the worst choice.

DISCLOSURE

The author reports no conflict of interest.

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[1]Article 3: "The objective of this Convention and its protocols is to protect present and future generations from the devastating health, social, environmental, and economic consequences of tobacco consumption and exposure to tobacco smoke by providing a framework for tobacco control measures to be implemented by the Parties at the national, regional, and international levels in order to reduce continually and substantially the prevalence of tobacco use and exposure to tobacco smoke".

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