Université de Montréal

Enjeux éthiques des communications directes aux patients par les compagnies pharmaceutiques

L'importance de repères éthiques pour mieux encadrer les activités de marketing pharmaceutique

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Thèse présentée
en vue de l'obtention du grade de PhD
en Sciences Biomédicales (option bioéthique)

Juillet 2017

Résumé

Il est consensuel d'affirmer que les patients devraient recevoir des informations équilibrées et crédibles leur permettant de prendre des décisions éclairées sur la meilleure façon de gérer leur santé. Les sources ne sont cependant pas toujours fiables et la recherche d'informations équilibrées, impartiales et compréhensibles peut être particulièrement difficile. Grâce à la richesse de son expérience en matière de marketing et ses ressources financières importantes (qui dépassent de loin celles des régulateurs nationaux), l'industrie pharmaceutique est l'un des acteurs majeurs en ce qui a trait aux communications directes aux consommateurs des médicaments (CDCM). Cependant, le marketing pharmaceutique est souvent considéré comme un vecteur transmettant des informations biaisées destinées à accroître la consommation de médicaments, au point où dans les dernières années, nombreux sont les appels lancés pour plus de régulation gouvernementale et pour que l'industrie autorégule mieux ses pratiques.

Bien que les CDCM soient généralement présentées de manière accessible et compréhensible, les pratiques des compagnies pharmaceutiques soulèvent (et sont influencées par) une tension importante entre deux impératifs conflictuels que sont la réponse aux: 1) attentes sociales pour l'information et l'autonomisation des consommateurs; et 2) attentes commerciales voulant que le marketing stimule la vente des médicaments et qui servent de référence pour évaluer la pratique des marketeurs pharmaceutiques. Ces deux impératifs justifient simultanément les pratiques pharmaceutiques, chacun auprès de différentes parties prenantes: le premier pour les régulateurs et les défenseurs des patients, et le second pour les acteurs et les actionnaires de l'industrie. Sans ces deux impératifs, la promotion des médicaments n'aurait tout simplement pas lieu: l'industrie n'investirait pas temps, argent et énergie, s'il n'y avait pas de gains financiers, et les pratiques n'auraient pas de légitimité sociale et réglementaire, si elles ne possédaient pas de qualités informationnelles.

La valeur sociale accordée aux CDCM, et la réponse régulatoire, varient grandement selon les juridictions. Seuls deux pays de l'Organisation de coopération et de développement économiques (OCDE), les États-Unis et la Nouvelle-Zélande, ont une approche permissive et

sont plus enclins à reconnaître une qualité informationnelle aux CDCM. La plupart des autres pays de l'OCDE (le Canada inclus) ont une approche plutôt prohibitive et ne permettent que les communications de sensibilisation aux maladies, de recherche d'aide et d'autres non directement liées à la vente d'un médicament. Bien qu'ils doivent coexister, les deux impératifs sont néanmoins souvent difficiles à concilier compte tenu des objectifs de commercialisation très élevés, découlant des attentes des marchés financiers, que les marketeurs pharmaceutiques se doivent d'atteindre. Il n'est donc pas surprenant que les activités de marketing présentent l'une des questions éthiques les plus discutées et les plus difficiles dans le monde contemporain des affaires.

Ceci, bien sûr, soulève beaucoup de questions en ce qui concerne la gestion et la résolution appropriées des problèmes d'éthique liés au marketing. Dans le cadre de cette thèse, ces considérations sont analysées à travers l'étude de quatre cas paradigmatiques permettant d'expliciter les enjeux éthiques et régulatoires que soulèvent les CDCM. Chaque cas est ciblé sur un dispositif communicationnel particulier et vise à dresser un portrait plus précis de l'impact de l'utilisation des CDCM, des considérations d'ordre social et des implications en termes réglementaire et éthique. L'objectif de chaque étude de cas, et de façon plus générale celui de la thèse, est d'émettre des recommandations quant à la responsabilité des principaux acteurs en vue de mieux encadrer la pratique marketing et baliser l'éthique des CDCM.

In fine, l'analyse des cas permet de mettre en exergue les dimensions éthiques les plus porteuses d'un changement systémique dans la pratique du marketing pharmaceutique. Sont dès lors ciblées les pratiques des employés de l'industrie, pour qui des repères sous la forme d'un engagement éthique ainsi que l'esquisse d'un cadre éthique sont proposés. L'idée est de cibler directement les acteurs qui, au quotidien, ont un rôle majeur dans le déploiement des CDCM, mais qui n'ont largement jamais reçu de formation en éthique leur permettant de comprendre les implications de leur pratique. L'objectif est d'aligner la pratique de marketing pharmaceutique aux attentes prosociales et d'équiper les marketeurs avec des repères éthiques clairs soutenant une pratique appropriée et morale du marketing pharmaceutique.

Mots-clés : autorégulation, bioéthique, industrie pharmaceutique, marketing, médicament

Abstract

It is widely accepted that patients should be provided with balanced and credible information so that they can make informed decisions about how best to manage their health. However, the sources are not always reliable and the search for balanced, impartial and comprehensible information can be particularly difficult. With a wealth of marketing experience and significant financial resources (far in excess of national regulators), the pharmaceutical industry is one of the major players in direct-to-consumer communications (DTCC). However, pharmaceutical marketing is often seen as a vehicle for transmitting biased information to increase drug consumption, to the extent that in recent years there have been many calls for more government regulation and for industry to better self-regulate its practices.

Although DTCC are generally presented in an accessible and comprehensible way, pharmaceutical company practices raise (and are influenced by) a significant tension between two conflicting imperatives: 1) social expectations for information and consumer empowerment; and 2) commercial expectations that marketing stimulate the sale of drugs and serve as a reference for evaluating the practice of pharmaceutical marketers. These two requirements simultaneously justify pharmaceutical practices, each with different stakeholders: the first for regulators and patient advocates, and the second for industry stakeholders and shareholders. Without these two imperatives, the promotion of medicines would simply not happen: the industry would not invest time, money and energy if there were no financial gains, and practices would not have social and regulatory legitimacy if they did not possess informational qualities.

The social value given to the DTCC, and the regulatory response, varies greatly between jurisdictions. Only two countries in the Organisation for Economic Co-operation and Development (OECD), the United States and New Zealand, have a permissive approach and are more inclined to recognize the informational quality in DTCC. Most other OECD countries (including Canada) have a rather prohibitive approach and only allow for disease awareness, help seeking and other communications not directly related to the sale of a drug. Although they must coexist, the two imperatives are nevertheless often difficult to reconcile given the very

high marketing targets, arising from the expectations of the financial markets, that pharmaceutical marketers must attain. It is therefore not surprising that marketing activities present one of the most controversial and challenging ethical issues in the contemporary business world.

This, of course, raises many questions regarding the proper management and resolution of ethical issues related to marketing. In the context of this thesis, these considerations are analyzed through the study of four paradigmatic cases as a means of explaining the ethical and regulatory issues raised by DTCC. Each case is targeted at a particular communication device and aims to provide a more accurate picture of the impact of DTCC, its social considerations and regulatory and ethical implications. The objective of each case study, and more generally that of the thesis, is to make recommendations concerning the responsibility of the main actors in order to better oversee marketing practices and to layout an ethics for DTCC.

Ultimately, the analysis of the cases highlights the ethical dimensions that are the most conducive to systemic change in the practice of pharmaceutical marketing. The cases are therefore focused on the practices of industry employees, for whom benchmarks are proposed, in the form of an ethical engagement and a preliminary ethical framework. The idea is to directly target the actors who, on a daily basis, play a major role in the deployment of DTCC, but who have never received training in ethics to enable them to understand the implications of their practice. The objective is to align the practice of pharmaceutical marketing with pro-social expectations and equip marketers with clear ethical benchmarks to support an appropriate and moral practice of pharmaceutical marketing.

Keywords : bioethics, drugs, marketing, medicine, pharmaceutical industry, self-regulation

Table des matières

Liste des tableaux

Liste des figures

Liste des sigles et des abréviations

CDCM : Communications directes aux consommateurs des médicaments

CSR : Corporate social responsibility

DE : Dysfonction érectile

DRF : Delays in the return of fertility

DTC : Direct-to-consumer

DTCA : Direct-to-Consumer Advertising

DTCC : Direct-to-Consumer Communication

DTCI : Direct-to-Consumer Information

eHCDr : Extended HCD regime

FDA : Food and Drug Administration (US)

HCD : Hormonal contraceptive drugs

IFPMA : International Federation of Pharmaceutical Manufacturers and Associations

IUD : Intrauterine hormonal devices

MS : Menstrual suppression

OCDE : Organisation de coopération et de développement économiques

OECD : Organisation for Economic Co-operation and Development

OMS : Organisation mondiale de la santé

PhRMA : Pharmaceutical Research and Manufacturers of America

PMDD : Premenstrual Dysphoric Disorder

R&D : Research and development

R-D : Recherche et développement

RFC : Relation fabricant-consommateur

RSE : Responsabilité sociale des entreprises

SOPK : Syndrome des ovaires polykystiques

WHO : World Health Organization

À tous ceux et celles qui croient que le changement est possible,
qu'il est réaliste de faire mieux et que l'éthique est primordiale.

Remerciements

Les remerciements servent tout autant à résumer une thèse que peut le faire la section Résumé. Ils présentent une autre facette et permettent de donner un aperçu des coulisses de la genèse, du développement, et de l'aboutissement d'une thèse. Il n'en sera pas autrement ici.

Je tiens d'abord à remercier Bryn Williams-Jones pour le soutien et l'encadrement lors de mes études doctorales, ainsi que de m'avoir donné les moyens de m'autonomiser pour devenir, je l'espère, un chercheur indépendant. Je tiens également à remercier Chris MacDonald pour cette heureuse rencontre. Tout au long de ma formation doctorale, j'ai eu le privilège de compter sur des mentors d'exception qui m'ont conseillé, facilité des opportunités de recherche et de financement ainsi qu'offert une parfois si nécessaire stimulation intellectuelle. Dès lors, je tiens à remercier Vardit Ravitsky, Isabelle Ganache, Jocelyne Saint-Arnaud ainsi que Béatrice Godard d'avoir eu sur moi cette influence positive.

Je tiens à remercier pour leur soutien financier les Fonds de recherche du Québec – Santé (FRQS), l'Unité SOUTIEN-SRAP du Québec et l'Institut de recherche en santé publique de l'Université de Montréal (IRSPUM) et l'Université de Montréal. Je me compte extrêmement chanceux d'avoir été financé tout au long de mon doctorat (et de l'être pour mon post-doctorat).

Je tiens à remercier l'ensemble de mes collègues de la première heure – Charles Dupras, Marie-Eve Lemoine, Christian Bergeron, Marjolaine Frenette, Elise Smith, Renaud Boulanger, Maude Laliberté, Charles Marsan – pour leur soutien, leur collégialité, leur bonne humeur et pour savoir animer les couloirs de Parc. Je tiens également à remercier Nathalie Voarino, Vincent Couture, Geneviève Rouleau, Louise Ringuette, Stanislav Birko et Anne-Isabelle Cloutier pour toujours embarquer dans mes idées folles.

Un merci spécial aux fruits (Pamplemousse et Pomme-Grenade) et à la fleur (Jonquille), nos discussions de fruits sont toujours des plus agréables. À Guillaume Gélinas, Simon Gélinas, Olivier Paré-Labrosse et Laurent-Karim Béland pour me garder en phase avec le réel (et l'irrationnel). À Frédéric Morand pour tout. À Alexandre Cabana, Simon Elgbeili, Ali El-Hage,

Julie Laffargue et Myriam Gosselin pour leur chaleureuse présence ainsi qu'aux amis suisses : Mathias Josset, Matthieu Pache, Julia Van Vleck Bradley et Laura Schroeder, pour leur accueil et leur gentillesse.

Un remerciement spécial pour les lieux qui m'ont accueilli tout au long de ma rédaction; notamment, aux cafés qui m'ont permis de rester bien plus longtemps que ma tasse vide aurait dû me le permettre, à la Bibliothèque Saul-Bellow de Lachine, et tout particulièrement à Laurent Han du Salon TeaShop, endroit où près de la moitié de la rédaction de cette thèse s'y est déroulée. À tous les auteurs qui m'ont inspiré et à la communauté Twitter pour son soutien.

Et je dédie le remerciement final à ma famille. D'abord et avant tout, à Victoria qui m'aura épaulé, (supporté) et soutenu durant ces années, qui a eu la folie d'accepter (en toute connaissance de cause) qu'on se marie. À Lisette pour toute la tendresse, la gentillesse et le soutien. À Dima, Grisha et Kappa de partager mon quotidien. Et à mes parents, toujours présents, aimants et patients. Pour la petite histoire : dès l'âge de 4 ans, quand on me demandait ce que je voulais faire quand je serais plus grand, alors que mes amis à l'époque voulaient être pompier, policier ou astronaute, je répondais que je voulais faire un doctorat. C'est grâce à tout le support reçu de leur part, que le souhait du petit garçon en moi se réalise enfin!

Merci à toutes et tous, l'aboutissement de ce doctorat est une œuvre collective, car sans tout l'appui reçu, soit il n'aurait jamais pris forme, soit il n'aurait pas été aussi épanouissant.

Avant-Propos

Alors que ma formation de premier cycle en physique me menait vers les sciences pures, mon intérêt pour le domaine de la santé et de la bioéthique s'est développé au fil de mon expérience dans l'industrie pharmaceutique au sein de laquelle j'ai travaillé, durant mes études, pendant 6 ans. En quelque sorte mon parcours au sein d'une des principales compagnies a suivi le cycle du médicament : j'ai travaillé trois ans en recherche clinique, un an en affaires règlementaires et deux ans en intelligence des affaires, ventes et marketing. La proportion des plages temporelles passées au sein de chacun de ces départements est même assez représentative de chacune des phases du médicament à suite à l'octroi d'un brevet : près de 8 à 10 ans en recherche clinique, une à deux années en attente de l'homologation par une agence règlementaire et environ 8 ans sur le marché avant que l'exclusivité de vente arrive à échéance.

J'ai eu la rare opportunité pour un chercheur de voir de l'intérieur comment un médicament est développé, défendu auprès des régulateurs, promu auprès des professionnels de la santé et vendu aux consommateurs. J'ai pu y constater l'ordinaire, le quotidien, les réussites et les échecs. Sans être alors dans une démarche de recherche, mais ayant déjà entrepris des études universitaires, j'étais déjà sensible à des enjeux éthiques qui, dans plusieurs cas, étaient induits par des pratiques souvent banales et répétitives pour les employés qui les menaient. J'ai eu l'occasion de voir et vivre des tensions éthiques entre les fins commerciales de la compagnie et des impératifs pro-sociaux, de discuter à « bâtons rompus » avec des vice-présidents et des directeurs et tenter de comprendre l'impact de leur industrie sur la société, selon leur perspective.

J'ai également eu l'occasion de travailler pour un organisme gouvernemental. Pendant un an durant ma maîtrise en bioéthique, j'ai agi en tant qu'assistant de recherche au sein du Commissaire à la santé et au bien-être du Québec. Le projet pour lequel j'ai été engagé visait à documenter et analyser l'état de situation de la place des médicaments avec pour but de susciter une réflexion sur leur utilisation au Québec. J'ai œuvré à documenter et brosser un portrait du développement des médicaments, de la régulation tout au long du cycle de vie du médicament

ainsi que de l'impact de l'industrie pharmaceutique dans l'économie québécoise. Le rapport produit par l'équipe du Commissaire servi à formuler des recommandations au Ministre de la Santé et des Services Sociaux du Québec.

Dès lors, la présente thèse est inspirée tant de mes recherches, des réflexions préliminaires amorcées dans le cadre de ma maîtrise que de mon expérience au sein de l'industrie. Je considère qu'il est possible d'avoir des pratiques en meilleure conformité avec les impératifs éthiques et les attentes pro-sociales. Cependant, selon mon expérience, j'ai pu constater que les employés des compagnies pharmaceutiques y sont sensibles mais ne sont pas bien outillés; ils n'ont trop souvent que les directives de l'entreprise orientées vers l'atteinte d'objectifs pour les guider dans leur travail et ne sont pas soutenus et protégés lorsqu'ils font face à des dilemmes. Généralement, ils vivent assez mal l'opprobre social à l'encontre de leur industrie, la qualifiant souvent d'incompréhension de la part des critiques quant à leur mission personnelle et désir de contribuer à l'amélioration de la santé humaine, nonobstant les agissements de leur entreprise. Incapacité à reconnaître la portée de l'influence omniprésente de leur industrie pour certains et sentiment d'impuissance pour changer les choses pour d'autres, les raisons sont nombreuses pour que l'industrie (et ses employés) perpétue des comportements à la moralité douteuse, et où pointe trop souvent le jupon de la profitabilité, sous le couvert d'une rhétorique bienveillante à l'égard des patients et de la société.

Cette thèse n'est pas une ethnographie des pratiques de l'industrie, mais plutôt une recherche conceptuelle et analytique ayant pour but d'arriver à établir des repères éthiques permettant de mieux guider les employés et de les outiller à reconnaître et à trouver un meilleur équilibre entre les intérêts commerciaux de leur employeur et ceux de la Société à laquelle ils appartiennent en tant que consommateur, patient, contribuable et citoyen.

Ni apologie des pratiques de l'industrie ni diabolisation, cette thèse est dédiée à ceux qui œuvrent et considèrent que le changement est possible, qu'il est réaliste de faire mieux et que l'éthique est primordiale; mais également à tous les autres, qui finiront bien par comprendre (avec un peu d'aide) que la moralité est inéluctable et *in fine* désirable.

Introduction

En tant que branche industrielle, le secteur pharmaceutique possède un statut unique par le double rôle qu'elle joue au sein de la société, à la fois lucratif et thérapeutique. Elle est ainsi constituée d'entreprises privées ayant comme objectif d'assurer leur rentabilité sur la base d'un modèle d'affaires qui s'axe sur le développement, la commercialisation, la distribution et la promotion de produits de soins de santé. Pour parvenir à ses fins, les pratiques marketing occupent une place cruciale en vue de rentabiliser les investissements et générer les profits attendus par les marchés financiers en œuvrant à maximiser la vente des produits (Applbaum, 2006). Le marketing fonctionne si bien que chaque dollar investi génère environ quatre dollars de vente pour la compagnie (Mintzes, 2009). Il n'est donc pas étonnant que les dépenses marketing soient plus importantes que celle menant à la découverte et au développement de nouveaux produits. Déjà, en 2005, un rapport de la Chambre des communes du Royaume-Uni, les principales compagnies pharmaceutiques dépensent entre 24% à 33% de leurs revenus provenant de la vente des médicaments, c'est-à-dire environ deux fois plus qu'en recherche et développement (R-D) (House of Commons Health Committee, 2005). L'un des constats du rapport est que l'industrie a une propension à difficilement concilier adéquatement ses deux rôles (générer des profits et contribuer à la santé des populations), notamment car : « The fundamental problem […] is that the industry is increasingly dominated by pressure from its investors and the influence of its marketing force and advertising agencies rather than its scientists » (House of Commons Health Committee, 2005, p. 8).

La question se pose donc s'il est réellement possible pour l'industrie de concilier ses deux rôles (profit et amélioration de la santé humaine), d'autant plus considérant son lourd historique de méconduite en marketing : « Marketing transgressions by manufacturers not only taint the image of both industry and medical practice but also raise doubt about the ability of regulators to deter illicit behaviors effectively. In efforts to define and then gain control over the situation, state and non-state entities have tried to align commercial practices with ethical and legal standards. » (Mulinari, 2016b, p. 1-2)

La réponse régulatoire est essentielle, cependant comme il sera illustré dans cette thèse, elle n'est pas à elle seule efficace pour guider les pratiques et assurer leur conformité avec les impératifs éthiques. Il est donc essentiel de mieux comprendre les pratiques et les contingences de l'industrie, de les engager dans l'alignement de leurs intérêts commerciaux aux attentes sociales. Cela appelle à la nature même de l'industrie, une industrie toute particulière, car elle génère des profits dans le domaine de la santé humaine. Est donc fondamentale, la reconnaissance de concilier les impératifs de profitabilité et de promotion de l'intérêt public. Ces dimensions doivent être à la base même de toute forme de régulation[1] et inscrite au sein des jugements normatifs qui sont faits à l'égard des pratiques de l'industrie. Cependant, il n'y a pas de consensus sur les standards éthiques qui devraient guider les pratiques de l'industrie ni sur ce qu'est une pratique acceptable. Bien au contraire, les attitudes et perspectives sont souvent rangées dans deux camps antagoniques, comme l'indique Katsanis (2016, p. ix) : « much of what has been written […] took one of the two extreme perspectives: either pro-industry or anti-industry, with little in-between ». Dès lors l'intérêt et la pertinence d'une réflexion éthique plus large et nuancée fondée tant sur une évaluation des pratiques et leurs implications que sur un questionnement des rôles et responsabilités des acteurs impliqués. Une telle posture permet d'aller au-delà d'une vision binaire et adversative pour plutôt adopter une perspective qui tient compte de la nature particulière de l'industrie, des produits qu'elles développent et commercialisent ainsi que des considérations éthiques distinctives qui incombent à ceux qui ont des pratiques lucratives dans le domaine de la santé humaine.

[1] Alors que les organismes de règlementation font désormais parties intégrales de la gouvernance des nations à travers le monde et que les codes règlementaires se sont imposés tant dans les discours publics, académiques que commerciaux, le terme *régulation* ne fait toutefois pas l'objet d'une définition unique et univoque (Koop et Lodge, 2017). Dans son sens le plus restrictif, la régulation se réfère à la: « promulgation of an authoritative set of rules, accompanied by some mechanism, typically a public agency, for monitoring and promoting compliance with these rules » (Baldwin, 1998, p. 3). Cependant, des interprétations plus globales définissent la régulation comme étant l'ensemble des efforts tant de la part des agences gouvernementales que de l'apport d'acteurs non liés à l'État en vue d'orienter l'économie (Beck, 2005; Strange, 1995). Cette interprétation élargie permet ainsi d'inclure, dans l'équation règlementaire, l'industrie comme acteur ayant un rôle important sur l'économie, sur l'établissement des attentes de conformité et dont les actions peuvent être autopolicées. La régulation représente donc les moyens dont se dote une société (gouvernement, comme acteurs économiques, sociaux et politiques) pour prendre en charge un ensemble de problèmes publics et de les soumettre à des normes. Elle est constituée de mécanismes institutionnalisés d'exercice du pouvoir et de guide pour la prise de décision où sont subsumées règles, normes et exigences par des documents ou des politiques qui visent à encadrer un problème public en question.

Faire des affaires (lucratives) en santé

L'industrie pharmaceutique[2] se conçoit elle-même comme étant unique en se définissant comme un « secteur des sciences de la vie » (Rx&D, 2015) avec la mission de « découvrir, développer et commercialiser avec succès des produits novateurs pour prévenir et traiter les maladies, soulager la douleur et améliorer la qualité de vie » (Novartis, 2015). L'industrie est, en effet, responsable de grandes avancées thérapeutiques qui contribuent chaque jour au sort des patients, tout en ayant des pratiques et des objectifs similaires à toute branche industrielle. L'objet commercialisé est distinct, mais ces pratiques sont classiques à celles des autres industries allant « du développement à la fabrication et la distribution, en passant par la commercialisation mondiale de médicaments » (AstraZeneca, 2015) avec comme mandat traditionnel d'« atteindre et maintenir d'excellents résultats financiers tout en offrant un service de valeur aux patients, aux consommateurs et aux gouvernements » (GSK, 2015). Un objectif qui est largement atteint avec des actifs mondiaux de plus de 950 milliards de dollars canadiens (LEEM, 2014) tout en jouissant, depuis plusieurs décennies, d'une profitabilité inégalée en comparaison aux autres secteurs industriels (Borch-Jacobsen, 2014).

Toutefois, au-delà des pratiques et objectifs classiques, le secteur demeure unique de par le caractère paradoxal de sa production. Le médicament, s'il contribue à améliorer la santé humaine, est également une cause de décès importante (troisième cause aux États-Unis) essentiellement due à des effets indésirables iatrogènes (Gotzsche, 2015). De cela découlent des enjeux moraux et sociaux qui ont mené à faire en sorte que le pharmaceutique est l'une des branches industrielles (avec le nucléaire et l'agroalimentaire) les plus régulées (Gagnon, 2009). Malgré la règlementation, le secteur fait l'objet de sévères critiques et d'une méfiance croissante de la part de la population (Borch-Jacobsen, 2014; LaMattina, 2013). Situation paradoxale qui pousse à s'interroger quant à la dualité des objectifs (profitabilité versus thérapeutique) que doivent mener de front les entreprises pharmaceutiques. Une dualité qui s'exprime à la fois de

[2] L'accent dans cette thèse est mis sur les entreprises qui développement et commercialisent des médicaments d'ordonnance protégés par un régime de brevets. En comparaison, les entreprises commercialisant des médicaments génériques (produits dont le brevet est arrivé à échéance) ont très peu de pratiques marketing s'adressant directement aux consommateurs.

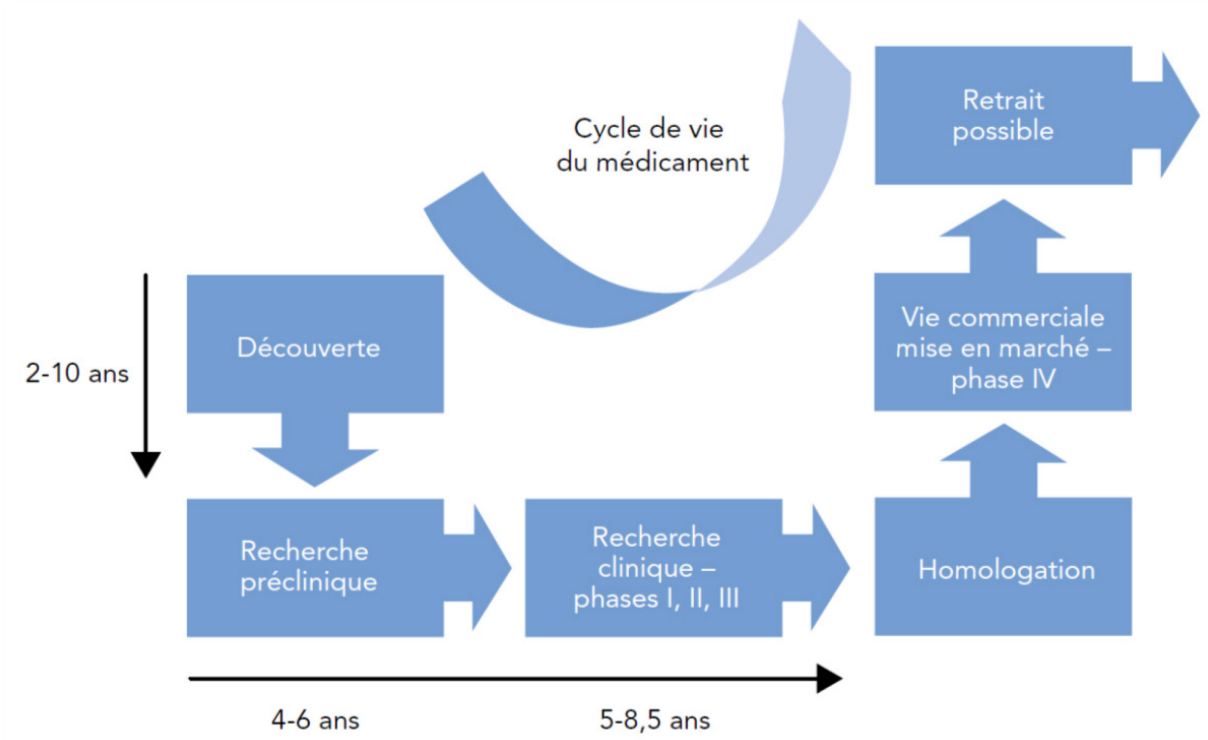
par la nature même du médicament, mais également à travers les activités commerciales en santé.

Le médicament comme produit

Au fondement de l'approche thérapeutique de la pratique médicale moderne, le médicament tire son origine étymologique du grec *pharmakon* qui signifie à la fois remède et poison, vie et mort. Cette polysémie est au fondement de nombreux questionnements dans la littérature dont les anthropologues et les sociologues de la santé sont très friands, exemplifiés par l'interrogation de Emily Martin (2006, p. 274) : « how do people keep ambivalence about drugs at bay enough to take them in the massive amounts that have made the pharmaceutical industry so huge and profitable, increasing many-fold in the last decade alone? » Le double potentiel des médicaments (mélioratif comme dépréciatif) étant très important et ayant forte influence sur les patients et sur le social, il n'est donc pas étonnant que les médicaments et les pratiques de l'industrie fassent l'objet d'une importante règlementation (Abecassis et Coutinet, 2008) de sa découverte à sa consommation.

Dans tous les pays industrialisés, des mesures existent, donc, pour contrôler le développement et la fabrication des composés pharmaceutiques qui sont protégés par un régime national de brevets émis distinctement par chaque pays (Gagné, 2010). Un ensemble important de lois, de règlements et de politiques encadrent chacune des étapes du cycle de vie des médicaments (voir Figure 1) : de la découverte et conception d'une molécule aux phases de recherche préclinique et clinique nécessaire pour obtenir l'autorisation des agences règlementaires nationales (par exemple, Santé Canada ou la Food and Drug Administration, FDA) en vue de commercialiser un produit (J.-S. Fortin, Bélisle-Pipon et Ganache, 2015). Le cycle de vie se termine par le retrait du marché du produit, processus plutôt rare, le cas échéant où il est jugé *post hoc* dangereux sur le plan de son innocuité ou inefficace.

Figure 1. Cycle de vie du médicament



Tirée de (Salois et al., 2014)

Un élément qui distingue tout particulièrement les médicaments d'autres produits est le fait que, dans les pays industrialisés, les médicaments doivent faire l'objet d'une approbation gouvernementale (homologation) et les patients ne sont pas autorisés à les acheter et les consommer à volonté. Les patients doivent impérativement passer par un intermédiaire, un prescripteur, qui à son tour à un pouvoir de prescription encadré et normé. Autant de particularités qui illustrent que le médicament n'est pas un produit commercial comme les autres, car il est à la fois un bien social (Canadian Pharmacists Association, 2009), un soin de santé (Canadian Medical Association, 2002), voire la représentation même du pouvoir thérapeutique de la médecine (Geest et Whyte, 1989). Qui plus est, les médicaments représentent un produit risqué, car tous les médicaments sont iatrogènes et ont des effets indésirables causant plus de 100 000 décès annuellement aux États-Unis, soit près de la moitié de l'ensemble des décès iatrogènes (Starfield, 2000). Cependant, les consommateurs ne sont généralement pas en

mesure d'évaluer ces risques et seuls ils ne peuvent donc pas donner un consentement libre et éclairé :

> Few consumers have sufficient technical or medical background to make rational and informed choices about therapeutic goods... For this reason, the selling of pharmaceuticals is restricted to protect consumers from possible health risks and deception. (Australia Trade Practices Commission, 1992, p. 19)

C'est ainsi, comme le souligne Marc-André Gagnon (2009, p. 8-9), le secteur pharmaceutique est : « one of the most heavily regulated by public authorities, and thus debates concerning this business are always partly political, and must be tackled not only from an industrial or economic point of view, but also using a political and social perspective ». Les médicaments et l'ensemble des acteurs les entourant ont donc un rôle important à jouer dans nos vies et ils ont gagné, au fil du temps, une place cruciale dans notre société d'où source de débat et de préoccupation sociale (Henry et Lexchin, 2002).

Les débats sur l'industrie pharmaceutique

Tant l'interface société et médicaments est particulière que peut l'être celle société-industrie. Qui dit grande place dans une société, dit également fortes critiques. Parmi les principaux reproches faits à l'industrie pharmaceutique : les marges de profits des compagnies qualifiées, par certains, comme étant excessives (Danielson et Lipton, 2012); le prix élevé des médicaments qu'ils soient novateurs (Gagnon, 2010; Lexchin, 2010) ou génériques (Skinner et Rovere, 2010); le développement des médicaments à éthique variable (Petryna, 2005, 2006); l'accès limité des patients à des traitements vitaux (Pogge, 2008; Pogge, Rimmer et Rubenstein, 2010), particulièrement dans les pays en voie de développement (Forman et Kohler, 2012); le lobbying intensif des compagnies auprès des gouvernements, les diverses formes de persuasion visant soit les patients, soit les professionnels de la santé (Angell, 2005; Bélisle-Pipon et Williams-Jones, 2015a, 2015b) et plus largement la valorisation des intérêts de ses actionnaires au-dessus des considérations et des intérêts de la société (Leisinger, 2005).

Du point de vue de l'industrie, ces pratiques, au centre des critiques, sont considérées comme cruciales pour ses intérêts, c'est-à-dire qu'elles permettent d'assurer sa performance, l'efficacité

et la rentabilité de ses opérations (Edgar, 2013). Cependant, les débats autour de l'industrie pharmaceutique sont d'autant plus fondés et distincts que rares sont les industries qui ont un impact direct tant sur la vie et la corporéité des populations, sur leur quotidien ainsi que sur leurs conditions de vie. À titre d'exemple, s'il est possible de critiquer l'imposante marge de profit de secteurs tels que les banques ou l'énergie, l'argumentation portera sur des considérations autres que la valeur prépondérante accordée à la santé dans notre société (Geest, Whyte et Hardon, 1996). Ainsi, la notion de santé transforme donc les enjeux éthiques liés au commerce ainsi que la relation fabricant-consommateur. Les implications de cette relation ne sont pas uniquement transactionnelles (contrairement à l'achat d'un vêtement[3]), mais s'incarneront (*embodiment*) dans la vie du consommateur, car s'il a besoin d'un médicament, le patient a incidemment un problème de santé (qui peut ou non être traité par d'autres moyens que pharmaceutiques). Il y a donc une condition de vulnérabilité qui est au fondement de la nécessité qu'un consommateur a d'entrer en relation avec l'industrie pharmaceutique et ses produits, ce qui n'est généralement pas le cas pour d'autres secteurs (énergie, télécommunications, mode, etc.). L'un des vecteurs qui cherchent à établir une relation entre les consommateurs et un ou plusieurs produits est justement le marketing pharmaceutique.

La place du marketing pharmaceutique dans les interactions industrie-médecin-consommateur

Le marketing pharmaceutique cherche à accroître son interaction avec les consommateurs et ainsi cherche à opérer une modification dans le modèle habituel des relations entre le fabricant et les consommateurs. Avant d'analyser cet impact, il convient d'abord de distinguer certains mots qui peuvent être traités comme synonymes soit : marketing, promotion et publicité.

Le vocable du marketing pharmaceutique

À des fins de clarté et de dialogue avec la littérature, la distinction utilisée sera celle qu'en fait Mulinari (2016a), soit la « *publicité* » est l'utilisation d'un média public pour attirer l'attention

[3] Toute industrie a son propre contingent de considérations éthiques. Par exemple, l'industrie du vêtement en étant fortement délocalisée dans des pays à faible revenu, elle est souvent critiquée pour les conditions de travail et l'état de précarité de ses travailleurs. Cependant, en soi le vêtement n'a pas pour fonction d'avoir un impact direct sur la santé de son porteur, il est donc un bien comme les autres sur ce plan.

sur un produit spécifique; la « *promotion* » est plus large et concerne toutes les activités et pratiques qui visent à augmenter les ventes; et le « *marketing* » comprend toutes les activités et pratiques promotionnelles, scientifiques et publiques qui alignent les produits et les consommateurs. Cette distinction est en phase avec la littérature en marketing où *publicité* (comme notion micro) réfère à « [a]ny paid form of non-personal communication about an organization, product, service, or idea by an identified sponsor » (Alexander, 1965, p. 9); *promotion* (comme notion méso) à « The coordination of all seller-initiated efforts to set up channels of information and persuasion to sell goods and services or to promote an idea » (Belch et Belch, 2008, p. GL11); et *marketing* (comme notion macro) à « the activity, set of institutions, and processes for creating, communicating, delivering, and exchanging offerings that have value for customers, clients, partners, and society at large » (American Marketing Association, 2013). Ces types d'activités forment un ensemble de moyens permettant d'accroître l'attention et la vente d'un (ou plusieurs) produit(s) (Canadian Marketing Association, 2013) et servent à la présentation et au renforcement tant de l'image d'un produit (par exemple, en le présentant comme étant le traitement standard) que de la marque de commerce d'une entreprise (Leiss, Kline, Jhally et Botterill, 2013). Dès lors, il est possible de représenter ces mots comme s'emboîtant l'une dans l'autre – comme une poupée russe, voir Figure 2 – décrivant des activités spécifiques (publicité) faisant partie d'un ensemble d'activités transversales à l'ensemble des pratiques de l'industrie (marketing).

Figure 2. Champ lexical du marketing pharmaceutique

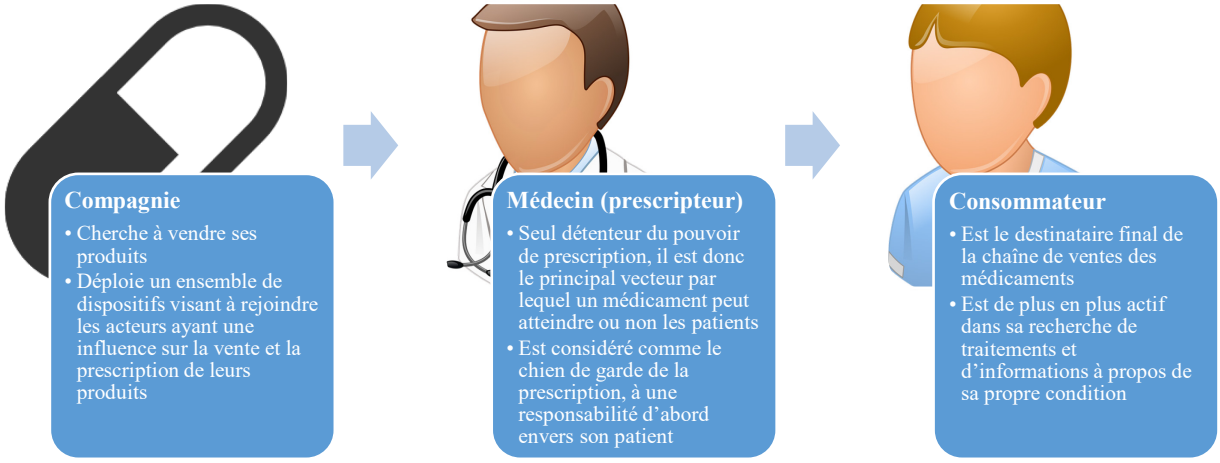
Cette vision du champ lexical du marketing pharmaceutique est en lien avec celle d'Applbaum (2006, 2009) qui considère que le marketing est plus qu'un type d'activités (parmi tant d'autres), mais est *in fine* le guide premier de l'industrie pharmaceutique. L'industrie a orienté l'ensemble de ses activités de recherche et de développement des médicaments sur la base de l'atteinte d'objectifs marketing, assurant ainsi l'alignement de ses produits aux consommateurs. Cet alignement peut se faire soit, en amont, par le développement de produits plus susceptibles d'être consommés par les patients, soit, en aval, de convaincre les consommateurs que les produits développés répondent parfaitement à leurs besoins. Ainsi, selon Applbaum, Mulinari et plusieurs autres auteurs comme Schwartz et Woloshin (2013), Sismondo (2004) et Steinman et collègues (2006), tant la R-D que la vente des produits sont des vecteurs du marketing.

Comment le marketing opère un changement dans la relation médecin-patient

Modèle classique : Compagnie-Médecin-Consommateur

L'objectif général du marketing dit classique, qui est permis dans l'ensemble des pays du monde, est de cibler les professionnels de la santé pour les informer et les encourager à traiter leurs patients avec un médicament en particulier (voir Figure 3). Ce modèle s'axe donc autour de trois grands acteurs : la compagnie promotrice et destinataire des communications promotionnelles, les médecins qui ont de la valeur du par le fait qu'ils détiennent le pouvoir de prescription, puis les consommateurs qui représentent l'aboutissement (*end points*) des médicaments. Le modèle peut donc être résumé par les lettres CMC et suit le narratif suivant : une compagnie lance une activité de promotion auprès des médecins pour les convaincre de l'utilité et de l'innocuité d'un médicament à prescrire à leurs patients. Dans ce modèle les patients sont passifs, puisqu'objets de la campagne de promotion : si la campagne porte ses fruits (donc que le médecin est convaincu), ils reçoivent une prescription, sans nécessairement savoir si leur médecin a été influencé par le fabricant.

Figure 3. Modèle classique du marketing pharmaceutique : Compagnie-Médecin-Consommateur (CMC)



La promotion des compagnies pharmaceutiques et les efforts qu'elles déploient à cibler les professionnels de la santé ne s'arrêtent pas qu'aux médecins : l'ensemble des professionnels de la santé sont inclus dans les plans marketing des compagnies, cela inclut notamment les pharmaciens et les infirmières. Cependant, considérant que largement ce sont principalement les médecins qui détiennent le pouvoir de prescription des médicaments et qu'en proportion les prescriptions sont quasi-exclusivement délivrées par les médecins, ils représentent des cibles bien plus intéressantes que tout autre professionnel de la santé[4], d'où l'intérêt de restreindre aux médecins, le modèle classique du marketing (modèle CMC).

Pourquoi l'industrie cible, depuis des décennies, les médecins? D'abord et avant tout, car ils sont considérés comme les gardiens des médicaments en agissant comme un filet de sécurité contre les usages inappropriés, car un patient ne peut se procurer un médicament vendu sous

[4] Les pharmaciens et les infirmières forment des cibles secondaires de plus en plus importantes et considérées par les compagnies dans le cadre de leurs activités marketing ciblant les professionnels de la santé. Cependant, ces professions ont un rôle moindre à jouer, car leur intervention survient après qu'un patient ait reçu une prescription. De par leur rôle de principaux distributeurs des médicaments, les pharmaciens sont également ciblés par les compagnies. Cela étant, les activités les visant sont d'un autre ordre. Une compagnie cherchera plutôt à rejoindre et influencer un pharmacien pour assurer qu'il tienne un certain produit dans son inventaire, ainsi qu'à lui conseiller d'user de son pouvoir de substitution (remplacer un médicament par un générique de la même classe) afin de vendre au patient le médicament de la compagnie. Ensuite viendraient les infirmières qui sont plus portées à administrer un médicament dans un contexte de soin.

ordonnance sans un acte médical (une prescription). Ils représentent donc une cible marketing privilégiée. De plus, bien que les professionnels de la santé croient largement le contraire, en arguant que leur comportement de prescription est rationnel et informé sur les données probantes, des études ont démontré que le marketing fonctionne et influence leur prise de décision (Murshid et Mohaidin, 2017; Pence, 1994; Peterson et Potter, 2004). À cela s'ajoute que considérer que le médecin ne soit pas non plus influencé par les demandes des patients est tout aussi fallacieux (Hollon, 2004).

Pour optimiser les activités marketing de tout type d'entreprises (peu importe le secteur d'activité), il est généralement conseillé de diversifier ses canaux de communication et de rejoindre le plus grand nombre de parties prenantes possible (Belch et Belch, 2008). Qui plus est, le marketing direct est généralement favorisé et moins il y a d'intermédiaires entre le promoteur et les consommateurs plus cela est considéré comme efficace (Laird, 1998). Il n'est donc pas étonnant que dans les années 1980, les fabricants aient commencé à faire pression sur la Food and Drug Administration (FDA) aux États-Unis afin de relaxer ses politiques et permettre la promotion aux consommateurs et qu'une situation similaire ait eu lieu au Canada (Mintzes, Morgan et Wright, 2009; Pinkus, 2002).

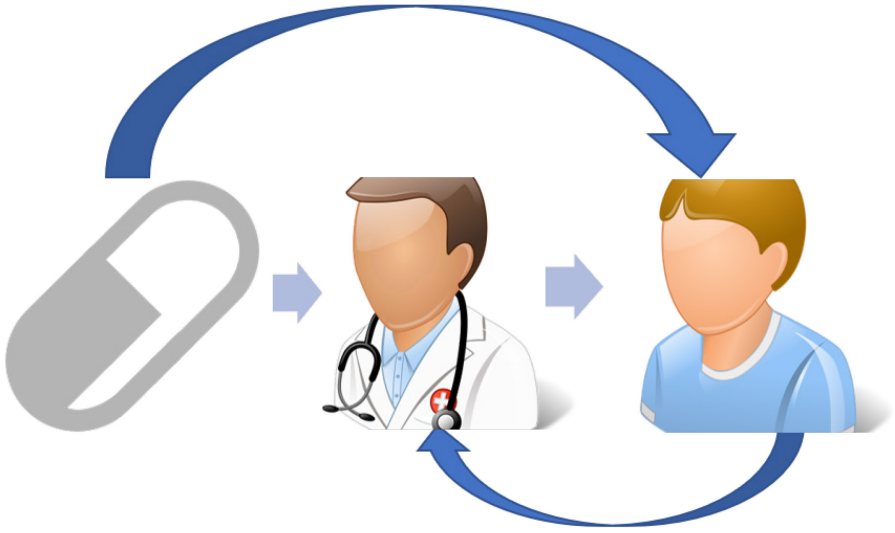
Les communications directes aux consommateurs : Modèle Compagnie-Consommateur-Médecin

Au sein des pratiques de marketing pharmaceutique, l'un des dispositifs marketing[5] les plus controversés consiste à communiquer directement avec les consommateurs[6]. Les communications directes aux consommateurs des médicaments (CDCM; en anglais, *direct-to-consumer communications*, DTCC) sont ainsi des moyens privilégiés à travers lesquels une compagnie peut rejoindre les consommateurs. De façon générale, il existe deux types de CDCM, celle utilisant un contenu promotionnel (*direct-to-consumer advertising*, DTCA), c'est-à-dire mentionnant le nom d'un médicament et faisant référence à ses revendications thérapeutiques, et celle n'ayant pas de contenu promotionnel (*direct-to-consumer information*, DTCI) qui véhicule des informations portant plutôt sur des conditions de santé cherchant à sensibiliser la population. Dès lors, le marketing direct aux consommateurs cherche à rejoindre et informer les consommateurs de sorte à les encourager à parler à leur médecin en vue d'obtenir une prescription.

[5] Sont appelés *dispositifs marketing*, les différents moyens qui sont utilisés par les compagnies pour parvenir à rejoindre leur public cible. De façon classique, les dispositifs de CDCM prennent la forme d'annonces télévisées, radiophoniques ou sous forme imprimés dans des revues, des magazines et des journaux. L'émergence de nouveaux moyens de communications et du recours à Internet a permis le foisonnement de CDCM électroniques comme des sites Web et des communications utilisant les médias sociaux. Finalement, les CDCM peuvent également être exempt de médium et se dérouler en présentiel où représentants pharmaceutiques et consommateurs peuvent échanger.

[6] Puisqu'il est au cœur même des communications des compagnies, il convient de définir ce qui est entendu par *consommateur*, ainsi que la raison pour laquelle cette appellation a été favorisée au profit de *patient*. Trois raisons ont largement motivé l'utilisation du mot *consommateur*. D'abord, du simple fait que l'appellation consacrée pour les communications des compagnies auprès des personnes ainsi que les lois et règlements font généralement usage du vocable de consommateurs. Ensuite, le terme *consommateur* appelle au côté autonome des individus, dimension qui est souvent mise de l'avant par le marketing. Finalement, ce mot est plus large que simplement celui de *patient*, car il inclut également les non-malades et les non-médicalisés : le *consommateur* n'a pas reçu de diagnostic et il n'est pas nécessairement un *patient*. Ainsi, le libellé *consommateur* est plus inclusif que celui de *patient*, car toute personne peut être un *consommateur* et être ciblée par les campagnes de l'industrie. Dès lors, alors que tous les patients sont consommateurs, l'inverse n'est pas nécessairement vrai. Certains pourraient critiquer l'usage du terme *consommateur* qui peut donner l'impression de banaliser le médicament, comme un bien de consommation comme les autres. Pourrait-on penser utiliser à la place le terme *consommateur-patient*? Ne serait-ce pas là une solution pouvant simplifier la problématique en prenant en compte les dimensions commerciales tout autant que fiduciaire qui incombent à ceux qui ciblent les individus pouvant être à même de nécessiter un traitement? En effet, cela pourrait être une option, mais à des fins de simplification, il a été décidé que le terme *consommateur*, plus inclusif et en phase avec la littérature, soit conservé.

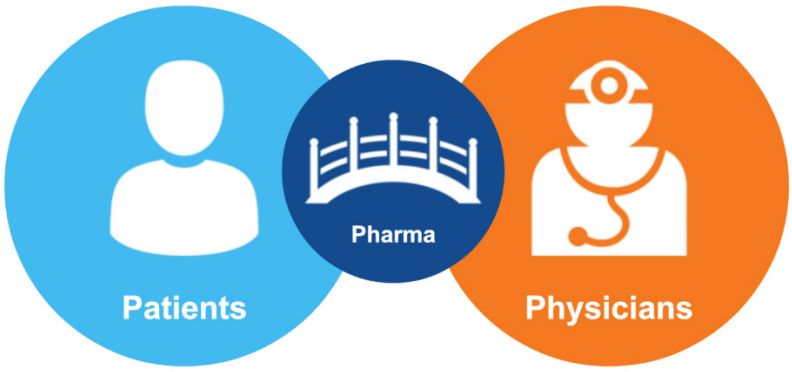
Figure 4. Modèle modifié du marketing pharmaceutique : Compagnie-Consommateur-Médecin (CCM)



Cette situation est représentée par la Figure 4, où le modèle classique a été modifié pour montrer cette voie de contournement. La grande flèche (au-dessus des acteurs) représente cette communication directe, sans intermédiaire, qui est recherchée par l'industrie. La plus petite flèche (en dessous des acteurs) représente ce que l'industrie espère que les consommateurs feront suite à l'exposition avec une CDCM, parler à leur médecin et leur demander une prescription pour le médicament en question.

L'inclusion du consommateur dans la chaîne marketing est vue comme étant éthique par les fabricants eux-mêmes dans la mesure où cela permet enfin de mieux prendre en compte et d'informer les consommateurs afin de satisfaire plus adéquatement leurs besoins (Richardson et Metcalfe, 2017) et ainsi : « conferring upon them the power of self-determination through choice » (Applbaum, 2006, p. 447). Ceci est directement en lien avec le rôle que désire revêtir l'industrie : elle se voit désormais comme étant le pont entre les patients et leurs médecins (voir Figure 5) en vue de mieux répondre aux besoins et aux attentes des patients et être un vecteur d'autonomisation.

Figure 5. L'industrie comme un pont entre les patients et leurs médecins



Tirée de Richardson et Metcalfe (2017)

Alors qu'est invoquée, par Richardon et Metcalfe (2017), l'importance de la centricité des patients comme voie d'amélioration de l'efficacité des activités de l'industrie, l'image pourtant utilisée par les auteures en est une où l'industrie est centrale au lien patient-médecins. On y voit donc une autre forme à travers laquelle l'industrie cherche à éliminer les intermédiaires pour se placer au centre des interactions, facilitant la communication d'informations portant sur les médicaments aux patients. C'est ainsi une façon de court-circuiter la relation classique CMC, en plaçant les activités marketing au centre d'un argument rhétorique bienveillant aux attentes et aux besoins des patients, ce qui légitimise les canaux de communications directs aux consommateurs. Selon De Jesus-Morales et Prasad (2017), ce type de court-circuitage est assez courant et cherche à induire des conflits d'intérêts et à coopter ceux qui détiennent une responsabilité fiduciaire envers la population (professionnels de la santé, politiciens, régulateurs, etc.). Défi d'autant plus important que les outils communicationnels tendent à être de plus en plus sophistiqués et performants. Aux dispositifs classiques (médias traditionnels) s'est ajoutés, au cours des deux dernières décennies, des modes de communications directes qui ont révolutionné le marketing et permettent désormais d'interagir avec les consommateurs (Katsanis, 2016). Cette croissance exponentielle de la puissance des outils de communication devrait s'accroître encore plus dans un avenir prévisible (passage d'un web 2.0 à un web 3.0) qui pourrait générer des défis sur le plan éthique encore plus importants.

Le secteur pharmaceutique est évidemment composé de personnes qui conçoivent et mettent en application les dispositifs marketing qui seront analysés. Ils sont des acteurs-clés dans

l'ensemble des tâches de « mise en scène » des médicaments afin de les rendre plus attrayants et ainsi, convaincre les consommateurs (et leur médecin) de leur utilité (Bélisle-Pipon, 2016b). Au quotidien, ils sont les premiers à faire face aux enjeux et dilemmes que posent leur pratique et les impératifs qui leur incombent afin de respecter les attentes de leur employeur et de la société (Ravelli, 2015). *In fine*, le cheminement de l'analyse et de la réflexion de cette thèse, quoique de portée générale, s'adresse de façon spécifique à ces employés qui font face aux défis éthiques dans un contexte où la rentabilité prime et est omniprésente.

Justificatif moral

Le marketing est indiscutablement l'activité la plus controversée de l'industrie pharmaceutique. Cela appelle à la contradiction même d'une industrie vouée au mieux-être de l'humanité, mais dont l'ensemble des activités sont orientées par la profitabilité de leurs produits. Cette idée d'une incompatibilité entre les visées publiques et commerciales à la base même des pratiques de marketing n'est pas nouvelle. Déjà en 1894 le psychologue William James indiquait que « the authors of [medical] advertisements should be treated as public enemies and have no mercy shown » (Laird, 1998, p. 235), il alla jusqu'à qualifier les activités de marketing pharmaceutique d'abomination.

Plus récemment, et dans la même veine, Kalman Applbaum s'est interrogé quant à savoir si le marketing est l'ennemi de l'innovation pharmaceutique (Applbaum, 2009). Il indique que « Precommercial planning and marketing demonstrates how the marketing-driven outlook in pharmaceutical companies today pushes these enterprises toward an escalation in the adoption of marketing rationales at the expense of public health » (Applbaum, 2009, p. 13). Il en vient à dire que l'industrie s'est cristallisée dans un système où la planification commerciale et le marketing sont en constante compétition directe et nuise à la recherche scientifique qui vise le développement de nouveaux traitements permettant de répondre à des besoins médicaux jusqu'alors non comblés. C'est plutôt cette dernière qui devrait être la mission première de l'industrie et la raison même justifiant un système commercial sur la base de produits thérapeutiques. Dès lors, il en conclut que le marketing, bien que légal, n'en est pas moins non-éthique lorsque des impératifs financiers l'emporte sur le développement de produits « *break*

through » (et non pas des médicaments « *me-too* » ou à faible valeur thérapeutique), et ce dans le cadre d'une industrie d'importance vitale pour l'humanité.

Ce problème de conciliation est également soulevé par les régulateurs : « Government has a dilemma: it has to balance the need to promote the competitiveness of this industry with the need to address health concerns and to promote the effectiveness of the [national health system] » (House of Commons Health Committee, 2005, p. 8). Constat similaire pour l'ensemble des gouvernements qui sont forcés de devoir jongler avec une pluralité d'impératifs (Saives et al., 2006). Cela mène à des constats candides quant à la difficulté de trouver un juste équilibre : « The Department of Health has constantly to balance trade imperatives and health priorities. This is a hard task. Sometimes, it means serving two masters at the same time » (House of Commons Health Committee, 2005, p. 8-9).

Cette tension entre les intérêts commerciaux/financiers et ceux de nature pro-sociale et éthique servira de fil conducteur tout au long de cette thèse, qui se centrera sur les enjeux éthiques et les bonnes pratiques marketing des communications directes aux consommateurs des médicaments. L'accent sera mis sur une analyse de l'état de la régulation encadrant le marketing pharmaceutique et son efficacité quant à baliser les pratiques commerciales ainsi que de faciliter le développement d'une réflexion et d'une prise de décision au sein de l'industrie instillée et soutenue par des repères bioéthiques. Seront ainsi explorés, à travers les pratiques de l'industrie et la régulation (tant formelle des gouvernements que s'auto-impose l'industrie), la déconnexion des activités des compagnies par rapport aux standards éthiques et aux attentes sociétales, mais également la capacité de la bioéthique à prendre en compte les dimensions commerciales sous-jacentes aux enjeux éthiques que soulèvent le marketing pharmaceutique.

Question de recherche

C'est dans ce contexte que le présent projet propose d'analyser les enjeux éthiques découlant des pratiques de marketing direct aux consommateurs sous l'angle du rôle et de l'influence des deux grands acteurs que sont l'industrie et les régulateurs. En raison tant des risques que les médicaments peuvent faire peser sur la santé que des valeurs sous-jacentes au marketing

pharmaceutique, tout un ensemble règlementaire encadre les pratiques de l'industrie. L'objectif est double : protéger les consommateurs et les rassurer qu'un système soit en place pour policer les pratiques non conformes. Dans le cadre de cette thèse, deux types de régulation seront traitées ayant chacune comme origine un acteur : l'*hétérorégulation*[7], venant des agences règlementaires, et l'*autorégulation*[8], venant des compagnies elles-mêmes.

Face aux enjeux éthiques importants que soulève le marketing pharmaceutique, une réflexion s'impose quant à savoir quels repères éthiques doivent guider tant l'hétérorégulation que l'autorégulation. La bioéthique est le champ d'études et de pratique qui se spécialise à identifier, comprendre et porter un regard normatif sur les pratiques et les technologies jouant un rôle sur la santé humaine. Cependant, elle n'est pas bien outillée à faire face aux dimensions commerciales sous-jacentes au modèle d'affaires et aux pratiques de l'industrie pharmaceutique (Brody, 2012). Qui plus est, comme l'indique Angus Dawson (2010), le regard bioéthique est trop souvent porté sur des enjeux d'éthique médicale, mettant l'accent sur les avancements

[7] L'*hétérorégulation*, parfois appelée *régulation formelle*, est établie et promulguée par une entité qui enchâsse et balise la conduite d'un certain ensemble d'activités menées par un tiers. Ce dernier est donc sujet aux normes établies et doit s'y conformer sous peine de sanction. Dès lors, l'auteur de l'hétérorégulation, comme un gouvernement ou une agence règlementaire, établit un ensemble de normes contraignantes, surveille leur application et sanctionne les récalcitrants. Il peut soit mener ses activités soit même, soit déléguer à un tiers ces responsabilités. Comme il sera vu dans le Chapitre 1, c'est le cas notamment au Canada, où Santé Canada est l'instance qui établit formellement la régulation portant sur le marketing des médicaments à laquelle l'industrie doit se conformer, mais elle a déléguée à certaines agences, telles que le Conseil Consultatif de Publicité Pharmaceutique (CCPP, cet organisme est plus connu sous son nom en anglais: Advertising Standards Canada, ASC) et les Normes canadiennes de la publicité (NCP, cet organisme est plus connu sous son nom en anglais: Advertising Standards Canada, ASC) les mandats de surveillance et de sanction. Malgré cette délégation, *in fine* Santé Canada demeure garant de la responsabilité de voir appliquée la régulation qu'elle a établie. Ainsi, à son tour, l'agence doit régulièrement surveiller l'application de la régulation qu'en fait le tiers, et s'assurer son respect à des fins d'intérêt public (telle que la protection du public).

[8] À l'opposé, au lieu de s'en remettre à une autorité qui lui est externe, un acteur peut s'autoréguler par l'adoption et l'adhésion à des normes, des exigences et des principes. C'est souvent sous la forme de codes (de conduite, d'éthique, de déontologie, etc.), de lignes directrices ou de guide des bonnes pratiques que l'acteur balisera les comportements qui seront jugés comme étant conformes à ce qui est attendu et ceux répréhensibles à bannir. L'*autorégulation* est donc un moyen à travers lequel est procéduralisée la gouvernance d'un acteur afin d'assurer la conformité et l'adhérence des comportements et des activités à un ensemble de normes et exigences satisfaisant ce qu'un tiers (comme le gouvernement ou certaines parties prenantes) considère comme étant approprié et adéquat. Du point de vue des compagnies, la régulation issue de leur association industrielle pourrait être perçue comme une forme d'hétérorégulation, au sens où l'association, en tant qu'entité distincte des compagnies, les associations nationales et internationales contraignent leurs membres à un ensemble de normes codifiées. Cela étant, les compagnies sont libres d'adhérer ou non à ces associations et donc cette régulation demeure autoimposée. Donc cela demeure de l'autorégulation provenant d'un collectif et non pas d'une seule compagnie. Au-delà de l'adhésion volontaire, les compagnies participent à la gouvernance de leur association et co-créent la régulation qui s'appliquera à tous les membres, il y a plutôt lieu d'y voir une forme de méta-autorégulation.

technologies, les cas cliniques et la réponse aux besoins immédiats d'individus. Cela a pour conséquence de reléguer au second rang les enjeux populationnels nécessitant une réponse règlementaire (ex. : par des politiques publiques) ou à des interventions populationnelles (ex. : en santé publique). Sur la base de la réflexion amorcée dans le cadre de ma maîtrise (Bélisle-Pipon, 2013), où a été réalisé une première ébauche de création d'un pont entre la bioéthique et les dimensions commerciales propre à l'industrie pharmaceutique, l'objectif est d'illustrer que la bioéthique peut jouer un rôle majeur pour faire la lumière sur les défis éthiques importants auxquels fait face l'industrie. En plus de considérer et commenter la responsabilité et les interventions du gouvernement, la bioéthique peut aussi accompagner l'industrie dans une transformation de ses pratiques. Cela requiert de pallier à certaines limites actuelles et de considérer plus largement la conciliation entre les impératifs commerciaux et populationnels, et de proposer des repères éthiques et des outils permettant à la bioéthique d'influer sur les pratiques de l'industrie.

Dans cette optique, la principale question de recherche à laquelle ce projet vise à répondre est la suivante :

> ***Face aux principaux enjeux éthiques que soulève la promotion des médicaments directement aux consommateurs, quels sont les repères (bio)éthiques qui doivent guider l'hétérorégulation et l'autorégulation de l'industrie?***

Une telle question de recherche implique de chercher à comprendre les conséquences, d'un point de vue éthique, de l'éventail des pratiques de CDCM sur les consommateurs ainsi qu'une analyse du rôle et de la responsabilité des acteurs ayant un rôle soit dans l'hétérorégulation ou l'autorégulation de ces pratiques.

Qui plus est, une seconde question sera transversale à la thèse soit :

> ***Comment la bioéthique peut-elle mieux soutenir les employés de l'industrie dans la conduite de leurs activités promotionnelles?***

À travers l'étude de cas représentatifs de large éventail de dispositifs marketing utilisés par l'industrie pour rejoindre les consommateurs mettant en lumière l'impact des pratiques de

l'industrie pharmaceutique et l'efficacité des mécanismes actuels de régulation, le but est de contribuer à bonifier le regard normatif qui est porté sur le secteur. Suivant une approche d'analyse de cas portant sur l'hétérorégulation des pratiques, il sera possible de dégager les principaux enjeux éthiques ainsi qu'offrir des pistes de réflexion et de solutions quant à l'autorégulation de l'industrie en vue de mieux réguler spécifiquement une pratique commerciale destinée à jouer un rôle mélioratif sur l'essor des consommateurs.

La recherche est fondée sur une posture pragmatique, reconnaissant le rôle essentiel de l'hétérorégulation, mais mettant l'accent sur l'autorégulation comme l'un des lieux où des avancées majeures peuvent être réalisées, car représentant une dimension largement négligée. Les grandes critiques faites envers l'industrie et les travaux des chercheurs visant à mieux comprendre les pratiques et/ou à bonifier le régime règlementaire des médicaments au Canada et ailleurs dans le monde serviront de trame de fond à cette recherche.[9] L'objectif de cette thèse est de parvenir à dégager des repères éthiques, adaptées et pratiques, permettant de baliser l'acceptabilité du marketing pharmaceutique et d'influer sur les pratiques de l'industrie, et ce essentiellement en agissant à la source de la génèse des enjeux éthiques que pose le marketing pharmaceutique, soit sur les pratiques des employés.

Structure de la thèse

Cette thèse est constituée de huit articles[10] et elle est divisée en sept chapitres répartis en trois parties. Chaque partie est développée de sorte à fournir un éclairage et des pistes de solution permettant itérativement de répondre aux questions de recherche. La **Partie I** porte sur ce que nous apprend le contexte, les spécificités des CDCM et la limite des cadres (bio)éthiques actuels. La **Partie II** cible l'hétérorégulation des différentes déclinaisons de CDCM, plus spécifiquement elle brosse le portrait des grands enjeux éthiques de l'état actuel de la régulation

[9] Ont notamment contribués à la réflexion les travaux de Mikkel Borch-Jacobsen, Marc-André Gagnon, Matthew Herder, Joel Lexchin, Barbara Mintzes, Shai Mulinari, Quentin Ravelli, etc.

[10] Le format de la thèse est par articles. Dans un tel format, il est possible qu'il y ait certaines répétitions entre les éléments présentés dans la thèse et le contenu des articles. Cela s'explique par le fait que les articles s'adressent à un auditoire particulier pour qui il est impératif de présenter des éléments contextuels, des arguments, une analyse et une conclusion qui peuvent chevaucher des éléments déjà présents dans la thèse. Dans l'ensemble des articles, ma contribution fut substantielle et j'en suis l'auteur principal. Alors que les idées majeures sont miennes, l'apport critique et dialogique des coauteurs fut essentiel et utile pour pousser plus loin les raisonnements et argumentaires.

des CDCM et comment elle forme les « règles du jeu » à travers lesquels les compagnies naviguent. Les limites de la régulation sont abordées et sont suggérées certaines avenues pour l'amélioration de son efficacité et de son utilité. La **Partie III** s'attarde sur les dimensions (bio)éthiques qui doivent guider les pratiques de l'industrie, c'est l'occasion à la fois d'énoncer les standards minimaux attendus ainsi que de proposer un cadre bioéthique que les entreprises peuvent instaurer et déployer afin de soutenir au quotidien leurs employés pour assurer des pratiques conformes tant aux impératifs commerciaux qu'éthiques et sociétaux.

Composition de chacune des parties

La **Partie I** ancre le contexte de l'éthique du marketing pharmaceutique, la définit ainsi que présente la pertinence de l'emphase sur les communications directes aux consommateurs des médicaments (CDCM).

Le **Chapitre 1** expose la problématique à l'étude : bien que les CDCM représentent moins de 10% des dépenses totales en marketing, elles sont l'une des pratiques les plus controversées en marketing dû à leurs impacts sur les consommateurs. Tant le portrait de différents types de CDCM que l'état de la régulation actuelle des CDCM sont présentés pour contextualiser l'environnement règlementaire dans lequel a cours cette pratique, mais également les arguments des défenseurs et des opposants à ce dispositif marketing. Finalement, les considérations éthiques majeures sont abordées dont l'impact des CDCM sur les consommateurs.

Le **Chapitre 2** présente une réflexion sur les outils analytiques qui devraient guider l'analyse des enjeux éthiques découlant des pratiques de marketing. Certaines limites de la bioéthique sont évoquées, d'où l'intérêt d'aller piger certains outils en vue de contribuer au développement et à la pertinence du champ de recherche et de pratique ainsi qu'à son utilité et sa pertinence à réfléchir et porter un regard normatif sur les enjeux incluant une dimension commerciale. L'article « What Can Bioethics Learn from Corporate Social Responsibility? » (Bélisle-Pipon, J-C. Soumis à *Medicine, Health Care and Philosophy*) présente ce qu'un concept comme la responsabilité sociale des entreprises peut apporter à la littérature en bioéthique en vue de porter un regard normatif mieux informé et permettant de délimiter les attentes raisonnables qu'il est

possible de faire poser aux compagnies pharmaceutiques. L'inclusion dans l'éthos de la bioéthique de concepts provenant de l'éthique des affaires peut permettre une meilleure reconnaissance et gestion des dimensions commerciales en santé. Cette discussion servira tout au long de la thèse à rappeler l'importance de prendre en ligne de compte les dimensions commerciales. Dès lors le regard normatif devra avoir pour objectif de tenter de concilier les impératifs commerciaux et sociaux découlant du double rôle de l'industrie.

La **Partie II** constitue l'analyse de cas, chacun des chapitres de cette partie présente l'étude d'un cas exemplifiant un dispositif de CDCM et de l'état de l'hétérorégulation qui l'encadre. Dans cette section est également présenté le continuum des CDCM sur lequel est basée la déclinaison des chapitres qui suivent. Est d'abord présentée l'approche méthodologique retenue pour l'analyse des cas à l'étude.

Dans le **Chapitre 3** est présentée la forme classique de CDCM, soit la publicité des médicaments à travers les médias traditionnels (télévision, radio et périodiques). L'article « Menstrual Suppression Advertisements: Rhetoric of Choice and Women's Autonomy » (Bélisle-Pipon, J.-C.; Ravitsky, V.; Doudenkova, V. & Williams-Jones, B. soumis à *HEC Forum*) se concentre sur les activités promotionnelles portant sur les médicaments induisant une suppression des menstruations. Le cas permet de brosser le portrait du dispositif marketing, tel qu'il est encadré et accepté aux États-Unis et à travers la rhétorique pharmaceutique il est possible de mettre en lumière les implications qu'elles ont sur les consommatrices et les enjeux éthiques qui en découlent.

Le **Chapitre 4** s'intéresse aux campagnes de CDCM qui font un usage d'Internet et des médias sociaux. D'abord, les articles « Drug Familiarization and Therapeutic Misconception via Direct-To-Consumer Information » (Bélisle-Pipon, J.-C. & Williams-Jones, B. (2015a). *Journal of Bioethical Inquiry*, 12(2), 259–267) et « Regulating Direct-to-Consumer Drug Information: A Case Study of Eli Lilly's Canadian 40over40 Erectile Dysfunction Campaign » (Bélisle-Pipon, J.-C. & Williams-Jones, B. (2015b). *Healthcare Policy | Politiques de Santé*, 10(4), 16-23) présentent une campagne d'information canadienne appelée *40desplusde40* (*40over40*) portant sur le traitement de la dysfonction érectile à canaux multiples : une campagne télévisée classique

encourage les consommateurs à visiter un site web visant à sensibiliser et encourager les consommateurs à consulter leur médecin pour le traitement de leur probable dysfonction érectile. Ensuite, est présenté un cas dystopique où, sur la base du *Big Data*, les pharmacies pourront géolocaliser les consommateurs et leur envoyer des informations ciblées ainsi que des escomptes sur le prix de certains médicaments. Scénario dont la probabilité s'avèrera dans quelques années, le cas – « Using Social Media to Sell Prescription Drugs » (Bélisle-Pipon, J.-C. & Birko, S. (2017), publié dans *ImpactEthics*) – présente l'une des rares formes permises au Canada de publicités directes des médicaments.

Le **Chapitre 5** présente la forme la plus interactive et directe (et pourtant la moins règlementée) que peuvent prendre les CDCM : les interactions en présentiel entre des consommateurs et des représentants pharmaceutiques. Découlant de l'expérience d'une patiente décrivant les activités auxquelles, elle a participé, l'article « Dating Patients: Wrong for Doctors but Acceptable for Drug Companies? » (Bélisle-Pipon, J.-C. soumis à *Health Politics, Policy & Law*) s'intéresse aux implications d'interactions sans interface, sans dispositif de transmission à distance des communications entre une compagnie et un consommateur.

La **Partie III** constitue la discussion de la thèse et, sur la base des constats de la Partie II, cible l'autorégulation de l'industrie.

Dans le **Chapitre 6**, sont résumés et analysés les principaux enjeux éthiques de chacun des cas de la Partie II à l'aune des quatre grandes théories éthiques que sont le conséquentialisme, déontologisme, éthique de la vertu et contrat social. Sur cette base est proposé, dans l'article « Pharmaceutical Marketing Ethics: Establishing the Ethical Standards to Support More Acceptable Practices » (Bélisle-Pipon, J.-C. et Williams-Jones, B. Soumis à *Ethics, Medicine and Public Health*) un encagement éthique comme boussole éthique visant à soutenir les employés dans la conduite de leurs activités de CDCM.

Le **Chapitre 7** table sur les repères éthiques établis dans le Chapitre 6 pour proposer une (ré)interprétation de l'éthique du marketing pharmaceutique en se basant sur deux propositions récentes dans la littérature portant sur la bioéthique pharmaceutique. Ainsi, l'article

« Pharmaceutical Marketing Ethics: Bioethics Frameworks as a Guide for Ethical Decision-Making of Industry Employees » (Bélisle-Pipon, J.-C. Soumis au *Journal of Bioethical Inquiry*) discute d'un ensemble de repères bioéthiques ainsi qu'une organisation permettant aux compagnies de soutenir leurs employés au sein des départements de marketing à « faire de la bioéthique » au quotidien afin que leurs pratiques répondent tant aux impératifs commerciaux que sociétaux.

La **Conclusion** résume brièvement tout le chemin parcouru dans le cadre de cette thèse. Elle présente aussi les limites ainsi que les recherches futures sur l'éthique du marketing pharmaceutique.

Partie I – Problématique

Chapitre 1 – Les communications directes aux consommateurs des médicaments

Au sein de l'éventail des pratiques de marketing pharmaceutique, les communications directes aux consommateurs des médicaments (CDCM) sont certes l'une des plus controversées. Les CDCM comprennent l'ensemble des mécanismes visant à rejoindre directement des consommateurs à propos d'un médicament d'ordonnance, soit à travers des moyens classiques comme les publicités à la télévision, à la radio ou dans des magazines, mais également par des sites web, des communications sur les médias sociaux ou en présence de représentants pharmaceutiques. Ces communications peuvent être réalisées dans le cadre de campagnes d'information tout autant que dans des campagnes promotionnelles.

Bien que les données exactes sur les dépenses promotionnelles ne soient pas disponibles (Eagle et Dahl, 2016), les estimations montrent une nette augmentation des dépenses en CDCM dans les derniers 25 ans : 166 millions de dollars américains étaient dépensés par l'industrie en 1993; 1,1 milliard de dollars US en 1998; 4,2 milliards de dollars US en 2005; et plus récemment, en 2016, ce serait près de 6 milliards de dollars US qui auraient été dépensés (Biegler et Vargas, 2016; Donohue, 2006; eyeforpharma, 2017; McCaffrey, 2017a). De ces budgets généraux en CDCM, l'industrie aurait dépensé 2,5 milliards de dollars US en 2016 spécifiquement pour des CDCM électroniques (sites web, médias sociaux), soit une augmentation d'environ 20% depuis 2013 (Huhmann et Limbu, 2016). La majeure partie des dépenses en CDCM sont faites aux États-Unis; pays qui représente, à la fois, le plus gros marché mondial pour la vente des médicaments et l'un des plus permissifs (Katsanis, 2016).

Ces dépenses en CDCM, bien qu'importantes et controversées, ne représentent que 7 à 9% de l'ensemble des budgets en marketing des compagnies pharmaceutiques (Geyer, 2011). Tout type de dépenses en marketing pharmaceutiques confondues (donc, incluant les CDCM, le marketing aux professionnels de la santé, le financement de l'éducation médicale continue, les

échantillons), certains auteurs estiment que les dépenses totales en marketing s'élevaient en 2004 jusqu'à 57 milliard $US (Gagnon et Lexchin, 2008). Cela amène donc au constat que les dépenses en marketing seraient près du double de celles en recherche et en développement.[11]

Année après année, une tendance lourde se dessine quant à la croissance des dépenses marketing visant à rejoindre directement les consommateurs. Les compagnies investissant de plus en plus pour rejoindre les consommateurs alors que leurs cibles marketing ont originellement plutôt été les médecins, seuls détenteurs du pouvoir de prescription.

La relaxation de la régulation et l'apparition des CDCM

Les CDCM sont relativement récentes, car elles ne sont permises que depuis tout au plus trois décennies. Traditionnellement, la promotion des médicaments avait pour cible et n'était permise qu'auprès des médecins, des pharmaciens, des cliniques et des hôpitaux à travers les revues médicales et les visites de représentants pharmaceutiques. Dans les années 1980, les compagnies ont fait pression de sorte à obtenir l'autorisation de communiquer directement avec les consommateurs avec des contenus promotionnels (DTCA). Pour les compagnies, cela représentait une opportunité nouvelle pour diversifier leurs efforts marketing afin d'influer sur l'utilisation de médicaments et, par le fait même, sur les ventes. Les CDCM ont été permises, d'abord aux États-Unis. La FDA exigea cependant à ce que les communications aient un juste équilibre (*fair balance*), c'est-à-dire que le message se devait de présenter de façon égale tant les bénéfices que les risques afin d'assurer une information équilibrée (Alperstein, 2014; Peyrot, Alperstein, Van Doren et Poli, 1998). L'efficacité et l'innocuité des médicaments étant une dimension centrale, notamment depuis le *Kefauver-Harris Amendment to the Food, Drug and Cosmetic Act* en 1962 qui requérait que les fabricants de produits pharmaceutiques démontre ces deux dimensions afin d'obtenir l'approbation de commercialisation pour un médicament d'ordonnance (Goodrich, 1963; Hollister, 1974).

[11] Les estimations varient selon les méthodologies utilisées. Gagnon et Lexchin (2008) estime qu'en proportion des ventes de médicaments, le marketing représenterait 24,4% des revenus tirés de la vente des produits alors que les investissements en recherche et développement s'élèveraient pour leur part à 13,4%. Pour sa part, Marcia Angell (2005) estiment, sur la base d'un rapport annuel de Novartis, que le marketing représentaient, en 2001, 33% des revenus tirés de la vente de leurs produits.

Depuis, parmi les pays membres de l'Organisation de coopération et de développement économiques (OCDE), seule la Nouvelle-Zélande a permis les contenus promotionnels dans les communications adressées aux consommateurs. Cependant, sous la pression de lobby de l'industrie (Arnold et Oakley, 2013), d'autres pays ont emboîté le pas à une certaine forme de relaxation de la régulation concernant les CDCM. C'est notamment le cas du Canada qui, dès la fin des années 1990, a assoupli ses restrictions en reconnaissant que l'industrie pouvait diffuser des communications non promotionnelles sur les médicaments afin de rendre ce type d'information plus largement accessible au public (Gardner, Mintzes et Ostry, 2003; Mintzes et al., 2009). Ainsi, la règlementation canadienne a permis à l'industrie pharmaceutique d'utiliser diverses stratégies, autres que les communications revendicatrices (*claim ads*) – dont l'interdit a été maintenu – afin de promouvoir ses produits (Gardner et al., 2003; Lexchin, 2013). Les « informations directes aux consommateur » (DTCI) – qui peuvent inclure des brochures et des sites Web, des annonces de recherche d'aide (par exemple, des annonces télévisées) et les médias sociaux – sont autorisées au Canada lorsque l'objectif putatif est de sensibiliser à une condition médicale particulière et à des traitements disponibles sans mention d'un produit ou d'un fabricant (Advertising Standards Canada, 2011). Cette distinction entre « publicité » non autorisée et « information » permise fut systématisée dans les dispositions de la politique de Santé Canada (2005) intitulée *Distinction entre les activités publicitaires et les autres activités*, qui inclut des considérations portant sur le contenu et contexte du message, les groupes ciblés, l'identité du diffuseur, le promoteur du message, l'implication du fabricant dans le contenu et la fréquence de diffusion.

Dans le cadre de sa règlementation, Santé Canada (2005) : « reconnaît l'importance que revêt, pour l'industrie pharmaceutique et le grand public, la diffusion, à des fins autres que publicitaires, de renseignements sur les médicaments destinés à la consommation humaine et l'accès à cette information ». De façon générale au Canada, toute forme de CDCM à caractère promotionnel doit respecter l'article C.01.044 du Règlement sur les aliments et drogues (C.R.C., ch. 870) : « Quiconque fait la publicité auprès du grand public d'une drogue sur ordonnance ne peut faire porter la publicité que sur la marque nominative, le nom propre, le nom usuel, le prix et la quantité de la drogue » (Government of Canada 2015, 871-872). En résumé, deux types de messages ont été autorisés au Canada : 1) l'annonce de rappel (*reminder ad)*, qui ne présente

que le nom du médicament, mais non son indication (soit une forme de DTCA), ou 2) l'annonce de recherche d'aide (*help-seeking ad*), qui présente uniquement une condition de santé – sans mentionner le nom d'un médicament ou d'une entreprise – et qui encourage les patients à consulter leur médecin pour plus d'informations (ces communications ont une visée non-promotionnelle et donc, ce sont des DTCI).

La supervision de l'application des dispositions de la *Loi sur les aliments et drogues* a été déléguée par Santé Canada à deux organisations indépendantes : le Conseil consultatif de publicité pharmaceutique (CCPP, mieux connu sous son appellation en anglais : Pharmaceutical Advertising Advisory Board, PAAB)[12] et normes canadiennes de la publicité (NCP, en anglais : Advertising Standards Canada, ASC)[13] qui ont des pouvoirs de recommandations, non contraignants, concernant les communications de DTCA et DTCI soumis volontairement par des sociétés pharmaceutiques.

Variabilité juridictionnelle

La relaxation de la régulation a connu un processus très variable d'une juridiction à l'autre. Alors que deux pays ont adopté des attitudes permissives[14], la plupart ont résisté à la dérégulation en autorisant que des campagnes visant à répondre à des objectifs de santé publique établis par le gouvernement : le Royaume-Uni n'a permis que la publicité des vaccins dans le cadre des programmes de vaccination approuvés par le gouvernement (House of Commons Health Committee, 2005). Il en est de même en France où certains produits pharmaceutiques peuvent faire l'objet de campagnes promotionnelles auprès du grand public s'ils servent des

[12] https://secure1.paab.ca/
[13] http://www.adstandards.com
[14] L'une des raisons notamment pour lesquels le contexte américain est si particulier est le fait directement lié à l'état de la liberté d'expression (free speech), tel que reconnu par le Premier amendement à la Constitution américaine, qui depuis l'arrêt Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n of NY en 1980 inclut également le discours commercial (commercial speech). Pour déterminer si une régulation limitant le discours commercial est appropriée, elle doit satisfaire aux quatre conditions du test Central Hudson : « First, as a threshold matter, to warrant First Amendment protection, the speech in question must not be misleading and must concern lawful activity. […] Second, to justify regulations restricting speech, the asserted government interest must be substantial. […] Third, the regulation must directly advance the governmental interest asserted 'to a material degree' […] Fourth, the regulation must be 'narrowly drawn,' and may not be more extensive than necessary to serve the interest. » ("US v. Caronia", 2012) Dès lors, c'est à la charge de l'État de prouver que sa régulation n'entrave pas la liberté d'expression commerciale.

objectifs de santé publique précis suivant l'avis Haut Conseil de la santé publique (HCSP) comme des vaccins ou des produits pour la cessation tabagique (Greffion, 2011). D'autres ont autorisé explicitement (Pays-Bas) ou tacitement (Australie) la DTCI. Les Pays-Bas ont autorisé les campagnes d'informations commanditées par les compagnies tant qu'elles sont de nature informative (Leonardo Alves, Martins de Freitas, van Eijk et Mantel-Teeuwisse, 2014; 't Jong, Stricker et Sturkenboom, 2004). L'Australie a commissionné, en 2000, une évaluation de sa législation (spécifiquement *Drugs, Poisons and Controlled Substances Legislation*) pour explorer la dérèglementation de la publicité directe au consommateur qui a conclu que cela aurait un impact négatif sur l'intérêt public (Galbally, 2001). Cela étant, les communications de nature non-promotionnelle et visant à sensibiliser la population à des conditions médicales précises (*disease-awereness*) sont permises (Australian Government Department of Health Therapeutic Goods Administration, 2011). Les mécanismes régulatoires australiens sont très similaires au contexte canadien : les annonces qui ne mentionnent pas le nom d'un médicament et qui visent à encourager les consommateurs à parler à leur médecin sont autorisées tout en étant encadrées par Medicines Australia, un organisme dit indépendant (comme le CCPP et les NCP), mais fortement associé à l'industrie pharmaceutique (Hall, Jones et Hoek, 2011).

Il existe donc une grande diversité juridictionnelle en termes d'attitudes permissive et prohibitive par rapport aux CDCM. Une variabilité d'autant plus grande que les États ne disposent pas de la même capacité d'établir des cadres règlementaires. Selon l'Organisation mondiale de la santé, seulement 20% des pays ont des agences et des processus règlementaires bien développés et opérationnels, 50% ont une capacité règlementaire très variable et modérément fiable tandis que 30% n'ont peu ou pas de capacité règlementaire (World Health Organization, 2003). La régulation des pratiques marketing est donc principalement une affaire de pays ayant les niveaux de produit intérieur brut les plus élevés, le plus souvent membres de l'OCDE.

Les médicaments les plus sujets à faire l'objet de CDCM

En raison de ses coûts élevés, la DTCC dite classique (qui s'opère par l'intermédiaire de la télévision, la radio ou les médias imprimés) est généralement restreinte aux médicaments ayant

le plus de potentiel à devenir des blockbusters (c'est-à-dire, des médicaments générant des ventes mondiales de plusieurs centaines de millions de dollars, voire de quelques milliards de dollars). Une étude récente de Greenway et Ross (2017) montre que les médicaments faisant l'objet des plus grands investissements en marketing ne sont pourtant pas ceux ayant une plus grande valeur thérapeutique. Les médicaments les plus promus seraient assez loin d'être ceux ayant la meilleure valeur pour la société :

> Compared with top selling and top prescribed drugs, the most aggressively promoted drugs in the US are less innovative, rated less favourably by Prescrire, and are less likely to be recognised as first line treatments by national guidelines, included on the WHO essential medicines list, and available as a generic. ... This raises concerns about the purpose of pharmaceutical promotion and its influence on patient care. [Our] findings suggest that pharmaceutical promotion should be met with healthy scepticism. (Greenway et Ross, 2017, p. 2)

D'ailleurs, les auteurs indiquent que les produits les plus efficaces, ayant la meilleure valeur sociale, nécessitent moins d'efforts promotionnels pour en assurer la vente. Pour ce qui est du Canada, une étude menée par Barbara Mintzes et collègues (2009) a montré que seuls quelques médicaments à succès sont fortement promus auprès des consommateurs. C'est ainsi que les huit médicaments les plus promus monopolisent 59% de la promotion totale faite au Canada. De plus, leur étude met en lumière que six de ces produits faisaient l'objet d'un *Avis de sécurité* par Santé Canada (c'est-à-dire que l'agence avait indiqué auprès du public et des professionnels de la santé que des risques liés au produit avaient été identifiés après l'approbation du produit) et que quatre s'étaient vus attribué un *black box warning* par la FDA (c'est-à-dire, un avertissement règlementaire que le produit peut causer de graves effets nocifs et que le médicament est interdit de publicité aux États-Unis). Compte tenu des restrictions canadiennes, du point de vue de l'industrie, il est tout simplement plus rentable de centrer la publicité sur les médicaments déjà connus du public, car la règlementation canadienne interdit de présenter les indications thérapeutiques du médicament. S'appuyer sur les blockbusters est susceptible de générer une exposition maximale aux consommateurs et ainsi, générer un plus grand retour sur l'investissement.

Dans la dernière décennie, les CDCM se sont transformées avec l'évolution des technologies de l'information (Katsanis, 2016). Les formes électroniques de CDCM (également appelée

eCDCM), soit les sites Web, blogues, médias sociaux, permettent désormais de promouvoir, à faible coût, tous médicaments qu'ils soient des blockbusters ou des produits nichés destinés à traiter des conditions rares (Mackey, Cuomo et Liang, 2015). La montée en popularité des eCDCM est également liée aux changements dans les comportements des consommateurs : compte tenu de la difficulté que de nombreux patients ont à obtenir des informations (c'est-à-dire accessibles et compréhensibles) sur la nature de leurs symptômes et sur la meilleure façon de les gérer, les consommateurs sont de plus en plus actifs dans la recherche d'information sur la santé, se fiant de moins en moins uniquement à leurs professionnels de santé (Dahl et Eagle, 2016; M. Harker et Harker, 2007). Dû tant à l'efficacité des CDCM pour augmenter la vente des produits et générer des profits qu'aux avantages des nouvelles formes, moins coûteuses, des eCDCM, les consommateurs n'ont jamais été aussi exposés aux communications de l'industrie pharmaceutique qu'ils ne le sont aujourd'hui (Campbell, 2009).

Utilité contestée

L'utilité même des CDCM – tant les communications promotionnelles (DTCA) que non-promotionnelles (DTCI) – est très contestée. De façon générale, le débat est campé entre deux positions souvent présentées (et se présentant) comme étant irréconciliables.

Pour

Les partisans des CDCM soutiennent que cela représente un dispositif important d'information des consommateurs à propos des traitements disponibles ainsi que leur permet de mieux connaître certaines conditions médicales, de chercher de l'aide pour eux-mêmes ou un proche et de mieux apprécier les options disponibles (Hollon, 1999; Holmer, 1999; Peyrot et al., 1998; Wong-Rieger, 2009). Selon Pharmaceutical Research and Manufacturers of America, organisme représentant les compagnies pharmaceutiques aux États-Unis, les CDCM ont comme bénéfices de permettre « an informed conversation about health, disease and treatments between patients and their health care practitioners » (PhRMA, 2008, p. 3). Les CDCM auraient ainsi pour objectif et conséquence d'éduquer les consommateurs sur leurs conditions médicales et leur donnant les moyens de comparer les options de soins disponibles tout en facilitant les discussions entre consommateurs et médecins (Hoek et Gendall, 2002; Shirreff, 2000). Les partisans soutiennent aussi que l'utilisation accrue de médicaments d'ordonnance encouragée et

générée par les CDCM a eu un impact positif et mélioratif sur la santé du public (PhRMA, 2008). Éthiquement parlant, les communications directes au consommateur sont généralement justifiées au motif qu'elles fournissent des informations pertinentes et impartiales permettant de promouvoir le choix éclairé et l'autonomie des consommateurs (Gilbody, Wilson et Watt, 2005; M. Harker et Harker, 2007; Meehan, 2015).

Contre

Les critiques des CDCM soutiennent que les communications sont plutôt trompeuses et biaisées, car elles ont tendance à mettre l'emphase sur les avantages et à minimiser les risques. Ceci amènerait les patients à croire qu'un médicament particulier fonctionne mieux, est plus efficace ou plus sécuritaire qu'il ne l'est en réalité (Schwartz, Silverman, Hulka et Appel, 2009). D'importantes préoccupations ont trait aux conséquences négatives – parfois vu comme des méfaits envers les consommateurs (Biegler et Vargas, 2016) – issues de l'influence de l'industrie sur le comportement des patients et des fournisseurs de soins de santé (notamment, la création de maladies, la surprescription et l'élargissement des usages des médicaments) (Applbaum, 2006; Mintzes, 2006; Perls et Handelsman, 2015).

Les opposants aux CDCM soutiennent que:

1) les communications directes affectent le discours des consommateurs ce qui les rend plus enclins à discuter des publicités qu'ils ont vu que la condition qu'ils pourraient avoir (Hughes-Morgan, Kendrick, Morgan et Stoltman, 2010);
2) les communications contribuent à l'augmentation des demandes et des attentes des consommateurs (Findlay, 2001), à exercer une pression sur les médecins (Lurie, 2009) et ont un impact néfaste sur la relation patient-médecin (Mintzes et al., 2003; Peyrot et al., 1998; Stange, 2007);
3) les consommateurs seraient moins insistants s'ils étaient plus conscients des risques, réduisant ainsi l'attrait des traitements médicamenteux induits par les communications (Karlowicz, 2009);
4) les communications favorisent les comportements de magasinage des médecins afin de trouver ceux qui seront prêts à leur prescrire le médicament désiré (Meehan, 2015);

5) les communications encouragent les consommateurs à demander à leur médecin de prescrire de nouveaux médicaments (ceux dont les brevets sont expirés ne faisant que très rarement l'objet de publicités) qui sont plus chers, sans démonstration que leur efficacité soit significativement plus grande que les médicaments de génération précédente, augmentant ainsi la pression sur les budgets des assureurs de la santé (publics ou privés) (Mintzes et al., 2003).

Autre critique fréquente, les dépenses en marketing sont considérées comme excessives, des sommes qui devraient plutôt être allouées à la recherche et au développement de nouveaux produits répondant à de réels besoins, et non pas des besoins générés par l'industrie. Comme l'indique Watkins (2012), l'innovation dans certaines classes thérapeutiques s'est largement limitée au marketing, et non pas au développement de nouveaux produits.

Ainsi, les pratiques de communications directes des sociétés pharmaceutiques ont été largement critiquées pour leur valeur d'information jugée problématique (Mulinari, 2016b), car elles créent des demandes inutiles des patients qui encombrent inutilement le système de santé (Frosch, Krueger, Hornik, Cronholm et Barg, 2007) et qui contribuent à une médicalisation accrue de la population (Mintzes, 2002; Mintzes et al., 2009). Que ce soit dans les messages à caractères informationnels (DTCI) ou promotionnels (DTCA), ces communications sont considérées comme des dispositifs visant à transmettre des informations susceptibles d'influencer ou de façonner certains comportements (Freudenberg, 2014) et l'information contenue n'est pas jugée comme suffisante ce qui peut nuire à la capacité des gens de faire un choix éclairé sur un traitement (Atkin et Beltramini 2007, Kessler et Levy, 2007). D'autant plus qu'il semblerait que les consommateurs ont tendance à se rappeler plus souvent des avantages potentiels des produits annoncés que les informations sur les risques (Schwartz, Woloshin et Welch, 2007; Sheffet et Kopp, 1990; Woloshin, Schwartz, Tremmel et Welch, 2001; Woloshin, Schwartz et Welch, 2004).

En plus des études critiques provenant de chercheurs, l'American Medical Association (2015) a récemment appelé le gouvernement américain et la FDA à bannir les CDCM aux États-Unis à cause des effets largement négatifs qu'elles ont sur les consommateurs, sur les relations médecins-patients ainsi que les coûts sociaux qu'elles génèrent.

Le fossé entre les deux camps demeure

Il existe donc un large fossé entre les partisans et les critiques des CDCM. Les premiers considèrent que ce genre de pratiques représente une situation gagnant-gagnant tant pour la compagnie que les patients alors que les seconds questionnent le rôle et la légitimité même de faire de la publicité pour des produits de santé, car visant à prioriser un intérêt commercial par rapport à des considérations de santé des populations.

La position critique semble être renforcée par deux éléments importants. D'abord, par la perception négative qui semble prédominer chez les consommateurs. Comme l'indique l'étude de Sullivan et Campbell (2015), une pluralité d'Américains croit que les CDCM (DTCA) n'incluent pas suffisamment d'informations portant sur les avantages et les risques des médicaments annoncés, ce qui suggère, selon les auteurs, que l'effet éducatif des CDCM est lacunaire et devrait être amélioré. Ensuite, par la littérature en marketing qui semble donner raison aux critiques. Selon Perry et collègues (2013, p. 729), le but d'une communication aux consommateurs n'est pas tant l'éducation ni l'autonomisation, mais plutôt :

> All advertising is intended to sell a product. In fact, successful marketing campaigns are often aimed at convincing consumers that their lives will be improved if they buy what is being sold. Generally speaking, informing the end-use consumer about product details is, from the perspective of the manufacturer, only necessary to the extent this information can be used to trigger a desire on the part of the consumer to purchase the product.

Dès lors, il convient donc de prendre en compte la dimension éminemment commerciale des activités marketing d'une compagnie : l'objectif premier d'une CDCM, du point de vue d'une compagnie, est de promouvoir la vente de ses produits. L'information véhiculée, définie essentiellement par la perspective commerciale, doit contribuer à cette fin. Ce constat est souvent repris par les détracteurs du marketing pharmaceutique qui considèrent, à l'instar de Matheson (2017), que : « Science is about objectivity, openness and truth. Marketing is about rhetoric, half-truths and sales. » La crainte est qu'au final, les CDCM aient pour effet que ce ne soit pas les produits les plus adéquats qui retiennent l'attention des consommateurs (tant et si

bien qu'ils ont un réel besoin d'une solution pharmaceutique), mais ceux avec les meilleures stratégies marketing et les campagnes les plus efficaces (Freeman, 1998).

Considérations éthiques sous-jacentes aux CDCM

Il est possible de dégager certaines considérations éthiques majeures que soulève les CDCM, telles que l'asymétrie informationnelle et les rapports de pouvoir et de vulnérabilité qui en découlent ainsi que les implications pour l'autonomie et les responsabilités afférentes. Le marketing, plus particulièrement la promotion et la publicité, est basé sur une économie de l'information au sein de laquelle les fabricants ont un double avantage informationnel par rapport aux régulateurs, aux professionnels de la santé, aux scientifiques et aux consommateurs (Bélisle-Pipon, 2013). D'abord, ils sont les seuls à posséder et connaître l'ensemble des données sur leurs produits tant concernant l'efficacité, l'innocuité que la somme des dépenses en R-D ayant permis le développement et la commercialisation d'un produit ce qui place automatiquement les autres acteurs dans une situation désavantageuse en termes d'informations. Ensuite, ils ont accès à un meilleur portrait (et plus détaillée) du marché de consommation, par des études de recherche de marché ou à l'aide de nouvelles technologies de l'information et de la communication, leur permettant de connaître et de rejoindre plus facilement et directement les populations les plus à risque d'avoir ou de développer une certaine condition (Ravelli, 2015), ou plus simplement celles qui sont davantage enclines à être convaincues par l'argument d'un message destiné aux consommateurs. De cette asymétrie découle inévitablement un rapport de pouvoir entre ces différents acteurs où le consommateur représente à cet égard le maillon le plus vulnérable.

La relation des consommateurs aux médicaments est donc complexe et est fortement liée à celle fabricant-consommateur. Cela étant, tous les consommateurs sont potentiellement vulnérables, car à tout moment leurs intérêts peuvent être injustement négligés et subir des préjudices moraux (Martin, Tavaglione et Hurst, 2014). Plus particulièrement, face aux médicaments, la vulnérabilité du consommateur est amplifiée par différents facteurs. D'abord, elle résulte des incapacités qui découlent de sa condition de santé (ex. : douleurs, fatigue, mobilité réduite, cognition diminuée, etc.) et des impacts potentiels que cela peut avoir sur sa vie (perte de

revenus, isolement social, stigmatisation, etc.). Ensuite, la vulnérabilité est exacerbée par la complexité de la connaissance scientifique biomédicale, faisant en sorte qu'un patient doit s'en remettre à des experts (comme ses professionnels de la santé) pour naviguer au travers des traitements, des soins et des changements dans ses habitudes de vie en vue d'améliorer soit une condition particulière, soit son état général de santé. Finalement, elle est influencée par l'accessibilité (ou le manque d'accessibilité) à des informations fiables, compréhensibles et neutres pour la population cible. Le consommateur se retrouve non seulement dépendant de l'information, souvent limitée, qui lui est transmise par les professionnels de la santé, mais aussi celle qui lui est véhiculée directement par l'industrie. Actuellement, le principal vecteur d'informations ayant le potentiel de toucher la population générale demeure le marketing pharmaceutique (Katsanis, 2016).

La solution à la vulnérabilité des consommateurs passe, dans une large mesure par l'atteinte d'une plus grande autonomie du consommateur, en particulier sur le plan de l'information, afin de lui permettre de faire des choix plus éclairés. Il est nécessaire de relever que le marketing pharmaceutique est souvent présenté (et se présente) comme promoteur de l'autonomie des consommateurs, ce qui permet une grande résonnance avec la bioéthique; surtout une bioéthique nord-américaine qui met l'emphase sur l'autonomie des individus comme principe souvent prépondérant (Wolpe, 1998, 2000). L'analyse des effets du marketing de Womack (2013, p. 276) est exemplaire pour illustrer la revendication de l'industrie à promouvoir l'autonomie : « The standard arguments appear to assume a simplistic correlation – more information means more agency for patients ». Une conception quantitative de l'autonomie, basée sur une surabondance d'informations, peut au contraire nuire à la capacité de jugement des consommateurs. Ceci se dégage notamment d'une étude récente, par Sivanathan et Kakkar (2017), qui indique que de mentionner l'ensemble des effets indésirables, tel que requis par la FDA, a plutôt l'effet de brouiller le jugement des consommateurs quant à la sévérité des effets indésirables; c'est ce que les auteurs appellent « l'effet de dilution ». Dès lors, trop d'informations nuit à un choix éclairé. Womack (2013, p. 276) indique que les recherches sur la façon dont les consommateurs comprennent, se souviennent et agissent grâce à l'information médicale « suggest that this relationship is much more complex than advocates would have one believe. » Qui plus est, un large ensemble de considérations contextuelles et environnementales,

sur lesquelles jouent les CDCM, affectent la prise de décisions en matière de santé et peuvent entraver les capacités des gens à faire des choix de santé (Ruger, 2010).

Il serait ainsi préférable d'encourager une meilleure littératie en matière de santé, favoriser le développement d'un regard critique face à la qualité et la pertinence de l'information véhiculée et autonomiser les consommateurs à agir sur leurs attentes en matière de santé. Ces éléments sont essentiels pour équilibrer le rapport entre industrie et consommateurs (Carter et al., 2010). Cette proposition, hors du propos de cette thèse, est une solution certes souhaitable, mais qui demeure à long terme. D'ici à ce que des propositions et des moyens substantiels provenant d'une variété d'acteurs soient déployés de sorte à agir efficacement sur l'autonomisation des individus, il est nécessaire de s'attarder à agir sur les forces en présence qui ont une influence tangible et directe sur l'information, la compréhension et la capacité de faire des choix éclairés au sujet des médicaments.

À titre d'étape intermédiaire, on peut penser à l'élaboration de repères éthiques pour mieux encadrer, soutenir et guider les pratiques marketing pharmaceutiques actuelles. Ces repères éthiques sont nécessaires à la fois pour l'hétérorégulation et l'autorégulation. C'est pourquoi un ensemble de responsabilités incombent aux fabricants du simple fait de faire commerce dans le domaine de la santé (Kohler et Gagnon, 2012). Comme le marketing a comme premier objectif la vente des produits de la compagnie, ce type de pratiques devra donc faire l'objet de régulation particulière considérant son impact indéniable sur la santé humaine. En effet, le conflit d'intérêts inhérent aux pratiques de l'industrie pharmaceutique (profitabilité versus santé) peut faire en sorte que : « [a] manufacturer will for commercial reasons wish to maintain or introduce a product which is from the public health point of view defective in terms of its efficacy, safety or quality, and that in such situations, the authorities must be capable of arresting the process until or unless the defect is remedied » (Dukes, 2005, p. 113). La régulation des pratiques a donc pour but de mitiger ce conflit d'intérêts et de protéger la population tout autant que de favoriser l'accès à des traitements efficaces et qui seront bénéfiques aux consommateurs (West, 2012).

Utilisation des repères éthiques par le secteur pharmaceutique

Au-delà des lois et règlements, un certain ensemble de repères éthiques existent déjà pour guider les pratiques de marketing de l'industrie (Francer et al., 2014). Qu'ils viennent d'autorités comme l'Organisation mondiale de la santé (OMS) (World Health Organization, 1988), ou établis de façon volontaire par des associations de compagnies pharmaceutiques (comme PhRMA aux États-Unis ou Médicaments Novateurs Canada), par des associations spécialisées en marketing (comme l'American Marketing Association[15]) ou par les compagnies elles-mêmes, ces guides visent à établir les standards éthiques guidant les pratiques considérées comme acceptables. En étant proactive sur le plan éthique, l'industrie se positionne comme voulant et ayant la capacité de surveiller ses propres membres afin d'assurer le respect des lignes directrices qui régissent le comportement de ses membres. L'établissement de tels repères a le grand avantage de réduire les pressions pour l'adoption d'une hétérorégulation plus stricte qui pourrait s'avérer moins favorable que les termes que l'industrie s'est auto-imposée (Katsanis, 2016).

Cependant, ces mécanismes de régulation fournissent des standards éthiques très généraux en vue d'informer les pratiques à l'échelle de l'industrie et au sein des entreprises. Ces orientations ne sont pas des cadres éthiques opérationnels qui peuvent être utilisés par les employés pharmaceutiques pour guider leurs pratiques quotidiennes et aider à résoudre les dilemmes éthiques. Par exemple, dans son Code d'éthique, Médicaments Novateurs Canada ne va pas au-delà de l'énoncé : « Members must provide full and factual information on products, without misrepresentation or exaggeration. Statements must be accurate and complete. They should not be misleading, either directly or by implication. » (Innovative Medicines Canada, 2016, p. 9) Seule PhRMA (2008) est plus explicite sur la question en établissant un ensemble de principes directeurs pour les CDCM, sans contextualiser l'usage de ces standards, les rendant sujets à interprétations. Pour sa part, l'International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) ne fait mention des CDCM dans aucun de ces codes ou de sa documentation (Francer et al., 2014). Pouvant laisser place à interprétation, ces directives et ces

[15] L'American Marketing Association (2017) a développé un engagement éthique applicable à l'ensemble des industries.

guides sont lacunaires et ne permettent pas de prendre en compte la complexité du contexte dans lequel ont lieu les CDCM, ni même leurs impacts sur les consommateurs et sur la société.

Dans son état actuel, tant l'hétérorégulation que l'autorégulation n'offrent que très peu de détails sur ce qui constitue une pratique éthique et adéquate : seuls de très larges engagements ou attentes décontextualisés sont énoncés. Il convient donc de reconnaître le besoin pour l'établissement de repères et de standards plus recherchés et informés tant par les pratiques réelles de l'industrie que par les théories morales et les principes bioéthiques.

Chapitre 2 – Vers une bioéthique pharmaceutique, habilitée à considérer les dimensions commerciales

Dans le présent chapitre sera explorée la nécessité de l'élargissement conceptuelle de la bioéthique pour arriver à mieux apprécier les enjeux spécifiques soulevés par les pratiques et le modèle d'affaires de l'industrie pharmaceutique; notamment comment reconnaître comme moralement pertinente la dimension commerciale essentielle au modèle d'affaires de l'industrie pharmaceutique. Il sera également démontré qu'un concept aussi important et utile au sein des entreprises que de l'éthique des affaires, soit la responsabilité sociale des entreprises (RSE), n'a pourtant jamais encore percolé en bioéthique alors que pourtant leurs épistèmes ont des similarités. Au final, l'objectif est de donner à la bioéthique les moyens de soutenir l'industrie dans sa conciliation des impératifs de profitabilité et de promotion de la santé pour des pratiques conformes aux attentes bioéthiques.

La bioéthique pharmaceutique : une opportunité conjointe pour la bioéthique et l'industrie

Après plus d'un demi-siècle d'existence, la bioéthique, bien qu'ayant abordé divers thèmes liés aux enjeux éthiques concernant l'industrie pharmaceutique (par exemple : conduite responsable des essais cliniques, biais dans la publication, conflits d'intérêts, etc.), n'est toujours pas en mesure de fournir une réponse pratique à des questions telles que celles relatives aux politiques publiques et aux pratiques ayant trait à la commercialisation et à la promotion des médicaments (Brody, 2012). Un large consensus se dégage quant au fait que tant les régulateurs que l'industrie (ses décideurs et employés, bien souvent à l'origine de ces enjeux) n'ont que peu de repères adéquats pour identifier, comprendre et gérer les questions de nature éthique entourant le médicament (Brian, 2012; Eaton, 2004; Lipworth, Montgomery et Little, 2013).

La bioéthique a pourtant un rôle important à jouer, pour autant qu'elle bénéficie d'outils lui permettant de l'assumer adéquatement. Il y a bien sûr des chercheurs en bioéthique qui, dans leurs travaux, abordent spécifiquement les enjeux entourant l'industrie en portant un jugement normatif de l'externe sur les pratiques de l'industrie (Applbaum, 2009; Brody, 2012; Elliott, 2001; Lau, 2005). Mais souvent, ils sont confrontés à des préjugés envers l'industrie, ou tout simplement face à une boîte noire (Abraham, 1995) et donc aveugle aux détails, aux processus

et aux influences qui guident quotidiennement la prise de décision au sein des compagnies. L'industrie elle-même reconnaît qu'elle a encore beaucoup à faire en termes éthiques (LaMattina, 2013). Un constat qui apparaît d'autant plus pressant que l'acceptation sociale des entreprises pharmaceutiques est dramatiquement basse dans un contexte global en profonde mutation où le secteur est confronté à un déficit d'innovation, à l'érosion de leur empreinte nationale et l'autonomie décisionnelle (souvent en faveur des pays émergents), à la fragmentation de la recherche (de plus en plus menée en partenariat avec une multitude d'acteurs, notamment avec des fonds publics et des universités), au manque de transparence de leurs opérations et à une méfiance importante à l'égard de leurs pratiques commerciales (Badcott, 2013; Bélisle-Pipon, Ringuette, Doudenkova et Williams-Jones, 2017; Busfield, 2006; Mulinari, 2016a; Spitz et Wickham, 2012). Cela pousse certains dirigeants de l'industrie, comme John LaMattina (ancien président de Pfizer Global R&D) à reconnaître que les entreprises doivent aller au-delà de leurs obligations de base (légale et économique) pour contribuer à l'amélioration de leur réputation et de leurs relations avec leurs parties prenantes (LaMattina, 2013). C'est donc une ère nouvelle qui force le secteur, face aux difficultés qu'il vit, à se réinventer d'où l'intérêt à l'aborder sous l'angle de l'éthique.

Dans les dernières années, sont apparus de nouveaux courants bioéthiques d'abord au sein même des compagnies puis plus récemment en provenance des universités, et qui sont orientés vers la compréhension et la résolution des enjeux éthiques soulevés par et entourant l'industrie pharmaceutique (Brian, 2012). Cette tendance émerge, de façon largement indépendante, selon deux principales sources : au niveau académique et au sein même des compagnies où les questions éthiques commencent à être abordées en soi (Brian, 2012). Plusieurs bioéthiciens de renom jouent un rôle actif comme consultants pour l'industrie, comme Tom Beauchamp et Robert Levine. À l'inverse, quelques compagnies se sont aventurées sur le terrain de la bioéthique, notamment Advanced Cell Technology, GlaxoSmithKline et Eli Lilly qui ont mis en place des comités d'éthique ou des groupes consultatifs en bioéthique. D'ailleurs, certains parlent désormais de la notion de « private sector bioethics » pour décrire cette bioéthique menée au sein de l'industrie, qui souvent se déploie au sein d'une entreprise en calquant les processus décisionnels des comités d'éthique de la recherche (Brian, 2012; Dresser, 2002, 2006). Il faut toutefois noter qu'un fort scepticisme entoure toute forme de bioéthique menée

par l'industrie (Brian, 2012; Brody, 2013; Elliott, 2003); Elliott (2004) qui demande même s'il est possible de faire confiance à une bioéthique menée et/ou financée par l'industrie. Bien que ces critiques visent juste quant aux craintes de l'instrumentalisation de la bioéthique, elles n'offrent que peu de solutions pour améliorer le regard normatif que l'on porte de l'extérieur (et souvent générateur du pharma-bashing), ni pour outiller les compagnies à mieux aligner leurs pratiques aux attentes sociétales, ni pour établir un cadre règlementaire ou des incitatifs rendant ainsi pragmatique et désirable pour les compagnies que de se doter de repères (bio)éthiques guidant la prise de décision.

Pourtant, la bioéthique serait appropriée considérant ses succès à guider la prise de décisions des individus dans des situations où des impératifs éthiques sont en conflit (Beauchamp et Childress, 2013). Pour réussir dans cette avenue, la bioéthique doit donc apprendre à soutenir l'industrie dans la conciliation de ses impératifs financiers et sociétaux. Elle se doit de développer un langage commun pouvant être compris tant de l'extérieur qu'au sein des entreprises. Elle doit aussi s'assurer que l'entreprise, non seulement reconnaisse ses responsabilités sociétales et accepte de se conformer aux attentes existantes, mais aussi instaure une structure permettant de soutenir les employés dans leur pratique quotidienne. Cela demande d'apprécier comme moralement pertinentes les dimensions commerciales : la bioéthique ne peut les ignorer au sein de son regard normatif et doit reconnaître que, dans le modèle d'affaires actuel de l'industrie pharmaceutique (et de tout autre type d'industrie ayant un impact sur la santé humaine), les considérations commerciales restent fondamentales tandis que la pratique des employés demeure assujettie aux dictats de la profitabilité. C'est pourquoi, c'est seulement à travers l'élaboration et l'utilisation d'un cadre d'analyse qui inclut au sein même de son éthos, à la fois la dimension commerciale en santé et les considérations sociétales et bioéthiques, qu'il serait possible d'aider à guider la résolution d'enjeux éthiques à large spectre en s'intéressant aux rôles et responsabilités des acteurs, et à leurs contributions effectives et attendues dans le partage des responsabilités.

Récemment, cet intérêt croissant pour le thème de la bioéthique en relation à l'industrie pharmaceutique a donné lieu aux premiers efforts de systématisation dépassant ces limites et incorporant la dimension commerciale, selon deux approches distinctes : celles d'universitaires

australiens Wendy Lipworth et Miles Little (2014), et celles d'employés américains de l'industrie, Luann Van Campen E. et collègues (2015). Quoiqu'elles se limitent aux seules considérations de recherche et de développement des médicaments (n'incluant ni la vente ni le marketing), ces deux écoles de pensée d'une (bio)éthique pharmaceutique se présentent comme étant de nouvelles lentilles théoriques et opérationnelles pour comprendre et résoudre les problèmes moraux entourant l'industrie. Sur la base de l'énonciation d'une bioéthique pharmaceutique, il y a donc une fenêtre d'opportunité intéressante qui se décline, tant par l'émergence de ces deux nouveaux outils théoriques pour la bioéthique (et donc contribuant à l'extension de son champ de compétence et d'application) que par la nature et l'ampleur des enjeux affectant l'industrie.

Exclus pour l'instant des propositions de bioéthique pharmaceutique, mais s'inscrivant dans ce champ nouveau, l'éthique du marketing pharmaceutique représente un thème d'étude d'autant plus pertinent que, jusqu'à présent, l'hétérorégulation n'est pas parvenue à rendre les pratiques conformes aux attentes sociétales. Une bioéthique pharmaceutique pourrait donc aider à balancer les considérations commerciales (que le marketing supporte) et sociales (auxquelles est conformée la bioéthique). Cela nécessite de reconnaître d'une part que l'industrie est un acteur important à la relation de soin et d'autre part, qu'elle doit se conformer à des impératifs bien au-delà de la simple profitabilité. Cela permet d'avoir envers elle des attentes de sollicitude, qui pèsent sur l'ensemble des acteurs impliqué dans la relation de soin aux patients (Cadoré, 1994). Évidemment, le marketing ne s'inscrit pas en soi dans la relation de soin en tant que tel, mais il en fait partie, au sens où elle a comme finalité qu'un consommateur ait accès à un produit thérapeutique. Il s'agit donc d'un aspect constamment présent, bien qu'en filigrane : cette inclusion au sein de la relation de soin ouvre donc la porte à une reconnaissance de l'industrie comme acteur et partie prenante importante, un acteur ayant un impact sur le social et des responsabilités sociales afférentes.

Il est, à cet égard, opportun de s'intéresser à un concept important provenant de l'éthique des affaires : la responsabilité sociale des entreprises (RSE), compris largement comme étant les responsabilités qui incombent à une entreprise envers la société dans laquelle elle opère. La démonstration qui suit sert à démontrer l'intérêt et la nécessité de l'inclusion des dimensions

commerciales en bioéthique, en reconnaissant que les entreprises, pour leur part, ont depuis des années déjà fait le chemin inverse en reconnaissant et cherchant à concilier leur responsabilité sociale à leur impératif de rentabilité. La discussion servira à comprendre comment la RSE peut aider à justifier et concilier les dimensions commerciale et sociétale. Également, cela permettra de montrer que ces dimensions ne sont pas incommensurables et qu'au contraire la RSE et la bioéthique ont des similarités importantes, notamment à travers le précepte de *ne pas nuire*. Finalement, plus largement, cela permet de mettre l'emphase l'intérêt d'inclure et légitimer les les compagnies à « faire de la bioéthique » ainsi que d'entamer une réflexion sur les moyens d'outiller les employés à reconnaître, réfléchir et gérer les enjeux éthiques, les tensions et les dilemmes qui se posent dans leur pratique quotidienne; démarche illustrée dans le texte suivant soumis à *Medicine, Health Care and Philosophy*.

What Can Bioethics Learn from Corporate Social Responsibility?

Bélisle-Pipon, J-C. Soumis à *Medicine, Health Care and Philosophy*

Introduction

An important part of the literature in bioethics is critical toward corporations – especially the pharmaceutical and medical devices industries – denouncing their relentless pursuit of profit-making and the influence this has on the health sector's actors (patients, health professionals, regulatory agencies, etc.) (Bélisle-Pipon, 2013; Rich et Ashby, 2015).

Corporate social responsibility (CSR) is an important concept in business ethics to conceptualize, analyze and operationalize the obligations that corporations have toward society and their stakeholders. Surprisingly, the bioethics literature does not use the concept even if bioethical issues often imply, or are triggered by, business activities and corporate behaviors, especially considering the essential role that companies can play in fostering human health (such as pharmaceuticals, medical devices, health insurances, etc.). For instance, Freudenberg and Galea consider that corporate practices have an important role in both the production of health and disease, thus they are a social determinant of health shaping health and behaviours (Freudenberg et Galea, 2008). It is therefore of interest and particularly relevant to better understand CSR and assess incorporating lessons and conceptual tools from CSR into bioethics so to help support the ethical provision of health products and moral assessments of business practices.

Distinction in the episteme of bioethics and CSR

Understanding of the epistemic differences between bioethics and CSR is crucial in order to analyze whether their natures makes them incommensurable or rather if it can serve as track to improve the relevance and operationalization of each of these fields of applied ethics.

First and foremost, it is important to understand what is at the foundation of their worldviews and their normativity. Bioethics focuses on health and living conditions, by seeking to (re)assess values, formulate and promote principles, to suggest solutions to moral dilemmas. Bioethics is more particularly concerned with the admissibility, from the point of view of moral values, of

what is continuously made possible by biotechnology, and what it implies for the value of life, the body and its marketization, for the "person" and his rights. On its part, CSR, as previously seen, is referring to the "responsibilities that a company has to the society in which it operates" (Hartman, DesJardins et MacDonald, 2014, p. 216). As a subset of business ethics, CSR operationalization aims at creating the right circumstances where prosocial behaviors are praised and business activities that ignore social demands are blameworthy.

Therefore, p*er se* their epistemes (i.e., what they seek to know) are different, but that does not mean that they are incommensurable. In order to capture and identify the common reality that is at the intersection of their objects of study, it is opportune to co-construct a common place for them to seize their respective reality and enable them to understand each other in order to be prescriptive about their joint reality: health-related business activities and concerns.

The incidence of the concept in the scientific literature

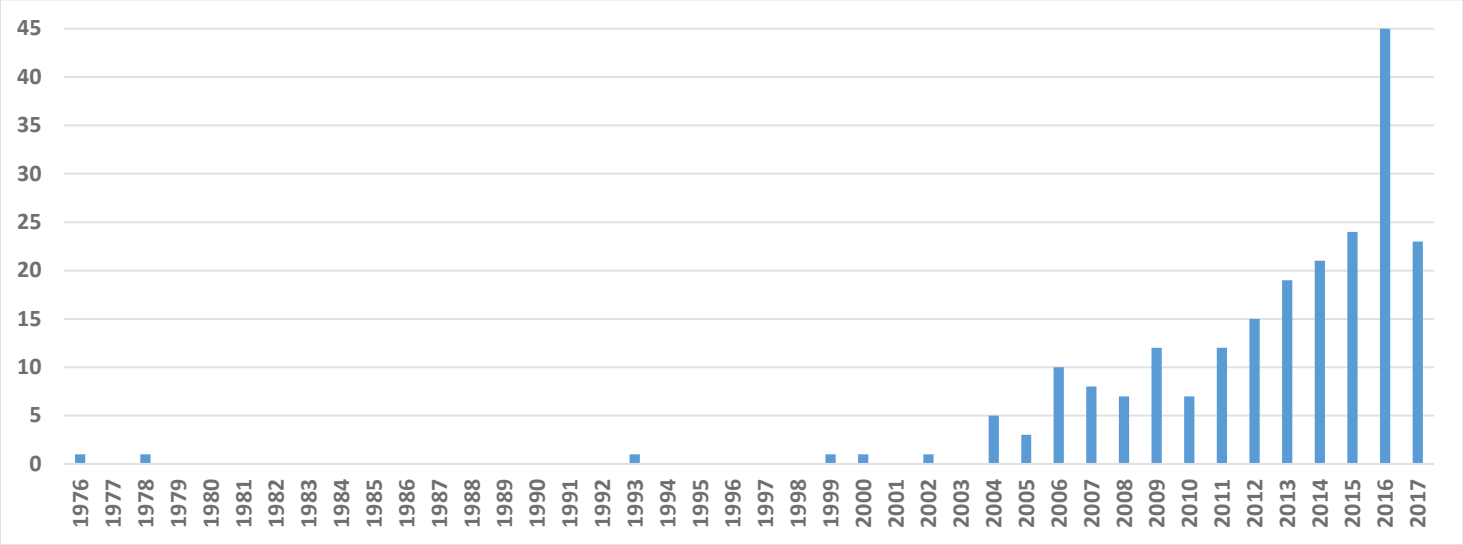
The concept is far from having been used or extensively analyzed in bioethics literature. In PubMed/MEDLINE, there are only three references[16] for CSR and bioethics: one by Ibrahim and colleagues (2000) and another by Brandão and colleagues (2013), both primarily related to hospital management (which is only remotely related to core bioethical issues), finally more recently a paper published by Hurst (2017) explored pharmaceutical pricing through the dual lenses of CSR and the UNESCO's Universal Declaration on Bioethics and Human Rights for reflecting on the societal responsibilities of pharmaceutical industry. In addition, a search in Web of Science reveals that one article by Lerga (2009) bears both keywords. Entitled "Bioethical Strongholds of Corporate Social Responsibility", the paper analyzes CSR relevance within bioethics, however being written in Croatian prevents most of its dissemination and use in the field. This lack of references shows that referral to the concept is not yet part of mainstream bioethics. Considering the essential role that companies can play on human health

[16] The search was done using PubReMiner version 1.31 on July 2 2017 with the query: "corporate social responsibility" AND "bioethics" AND ("journal article"[PT]). It is possible that there are more conceptual bridges between bioethics and CSR than this search may suggest, and that have not been identified by these keyword.

(such as pharmaceutical, medical device, insurers, etc.), it is surprising that such an important concept has been ignored in bioethics literature.

That being said, references to CSR are not that scarce in health sciences literature. In PubMed/Medline, 217 articles are including a reference to the concept (see Figure 6) but most of these articles are treating subjects related to tobacco, environmental management, public health, pollution and addictions. Interestingly, even if the concept is almost a century old, references to CSR seems to have gain traction, in health publications, almost exclusively in the last decade, as 89% of the references are from articles published between 2007 and 2017.

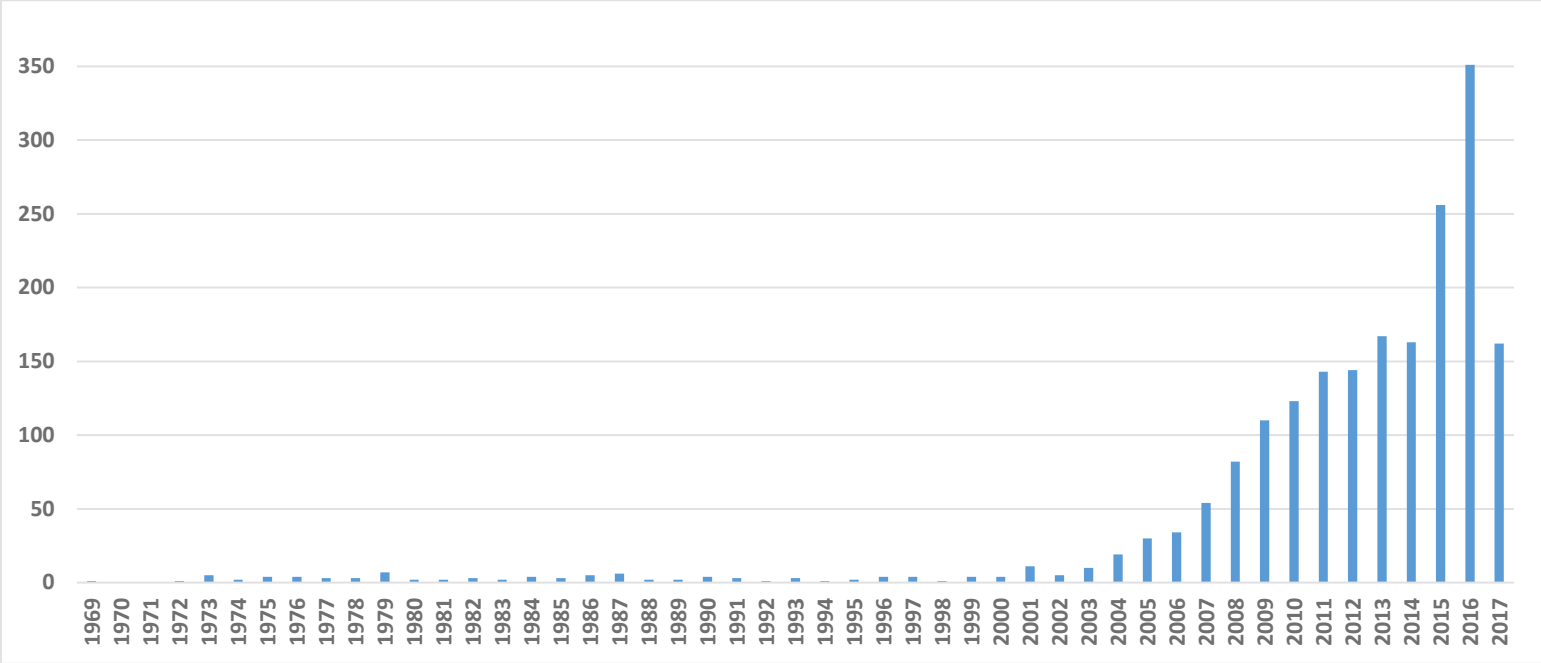
Figure 6. References of CSR in PubMed publications from 1976 to 2017



Source: PubReMiner version 1.31, July 02 2017, query: "corporate social responsibility" AND ("journal article"[PT])

That being said, this trend is in line with CSR general literature which also largely taken off since the early 2000s, reaching its apex in 2016, with over 1,956 articles published using, in a way or another, the concept. As seen on Figure 7, the general trend (including all research fields) is similar from the one in PubMed, but the total of references is much larger in the general literature than the one specialized on health and medicine.

Figure 7. References of CSR in Web of Science (including PubMed/Medline) publications from 1969 to 2017



Source: Web of Science, July 2 2017,
query: TI=("corporate social responsibility") AND DOCUMENT TYPES: (Article)

Why a concept so present in scientific literature, is so absent in bioethics to understand health and biomedical businesses-related issues? Are bioethics and CSR epistemologies incommensurable to the point that it is not possible to reconcile them in order to better understand issues that arise at the intersection of the corporate world and human health? What can bioethics learn from CSR? These are the questions this paper aims to answer: first, by a presentation of what CSR is through its different definitions and interpretations as well as some of its limitations; then, the contextualization of CSR within the activities of pharmaceutical companies, using drug promotion activities as a case study. Finally, a discussion of CSR's and bioethics' episteme will help understanding that the two applied ethics domains are not incommensurable, while the conclusion is that the concept of corporate social responsibility presents many benefits that could help enhance bioethical understanding of companies' behaviors and obligations, as well as representing future perspectives in bioethics.

What is Corporate Social Responsibility?

In order to understand what can be learned from corporate social responsibility, it is important to understand its origins, various interpretations, its operationalization mechanisms and some of the criticisms levelled against it.

The origins of CSR

Corporate social responsibility is as old as the history of modern business ethics and its emergence is associated to a change in the nature of corporations. At the turn of the 20th century, the model of large companies had grown from a property owned by a few, to a wider and dispersed ownership (Heald, 1970). The rise of shareholder-owned companies had two main consequences: 1) it contributed to the reduction of shareholder control on business management; and 2) because of its size and indirect owners' influence (now that companies are led by non-owner paid executives), the nature of companies changed to become institutions by themselves. So the emergence of CSR goes hand in hand with the rise of large companies, accumulating power and influence over the society, and of their responsibility, as new institutions, in the exercise of their activities (Acquier et Aggeri, 2008). It is in this context that a discourse began to emerge on the implicit contract between the corporation and society (Heald, 1961).

There are several historical analyses and interpretations of the emergence and consolidation of the concept. While some even trace the concept in the writings of Adam Smith, father of modern economics (Brown et Forster, 2013), Miller and O'Leary (1989) state that the concept was present in the debate on the transformation of US capitalism at the end of the 19th century as well as in the professionalization of management, as a result of the appearance of business schools (Heald, 1961). Hopkins (2003) retraces the early forms of CSR in academic writing to Merrick Dodd (1932), who advocated for the dual functions of a corporation, which are social-service and profit-making. Regardless of its exact origin, the most influential work comes from Howard R. Bowen's 1953 book *Social Responsibilities of the Businessman* (Acquier et Gond, 2007; Carroll, 1999). In his book, Bowen (1953), a Keynesian economist, acknowledged the economic development in American society of the 1940s and 1950s and suggested the doctrine of "social responsibility" referring to the idea that the initiative of businessmen can contribute to a better alignment between, on the one hand, managerial decisions and, secondly, the

economic and social objectives. Thus, according to Acquier and Gond (2007), Bowen clearly adopted society's concerns for social welfare maximization over the corporate profitability. Bowen's work has played an important role in shaping the contemporary problematization of CSR and in disseminating the concept, and since then the concept of executives' responsibility has received considerable attention and been at the center of debates (Acquier et Gond, 2007). Thus, the first structuring of CSR revolved around executive responsibility and to state that the companies had not only the role of making profit, but also have a social function. In reaction to these debates, Milton Friedman, renowned economist and Nobel laureate, made the following famous declaration in the Wall Street Journal (WSJ):

> In a free-enterprise, private-property system, a corporate executive is an employee of the owners of the business. He has direct responsibility to his employers. That responsibility is to conduct the business in accordance with their desires, which generally will be to make as much money as possible while conforming to the basic rules of the society, both those embodied in law and those embodied in ethical custom. (Friedman, 1970)

For Friedman, a manager's first and foremost responsibility is to generate profit for shareholders. Engaging with CSR is symptomatic of a conflict between executants and owners, considering that CSR is done at the expense of shareholders and resources invested in CSR would have been socially more profitable if they were instead invested in fostering firm efficiency (McWilliams et Siegel, 2001). Friedman's statement was one of the milestones that marked an important (at least symbolic) split between the different visions of CSR.

Then followed a prosperous period where a plethora of definitions were suggested in order to answer and better define CSR's relevance and performance to unravel and analyse business practices. From the 1960s to the 1990s, the debates about CSR were mainly theoretical and conceptual (empirical studies really began in the 1990s, and represent half of the papers published on CSR (Aguinis et Glavas, 2012, p. 935)). It is at this time that the great majority of CSR schools of thought appeared and that the definitions have become more complex; moving from visions oriented only towards profit to the incorporation of responsibility toward a more comprehensive inclusion and understanding of company's stakeholders, as well as the emergence of procedural models and more normative ones.

More recently, it is with the advent of market globalization and the acceleration of international trade that there has been an increased surge of interest in CSR (Mishra et Suar, 2010). This is mainly attributable, on one hand, given the growing complexity of the business world, to the volition to provide transparency in business activities and their behaviors in different geographical areas in which they operate (Jamali et Mirshak, 2006). On the other hand, the failure of some States to regulate and oversee concerns of national importance (e.g. infectious diseases, malnutrition, hygiene problem and illiteracy) (Margolis et Walsh, 2003) and the engagement of some companies in self-regulation to fill global gaps in legal regulation and moral orientation (Scherer and Smid, 2000) have also contributed to CSR's attention. In the same sense as with the transformation from family-owned companies to shareholder-owned ownership, the transformation of companies into multinationals had the effect to multiply the number of its stakeholders and to complicate their relationships and responsibilities towards them. The business environment never ceasing to become more complex, the concept of CSR is evolving in order to adapt to changes, properly grasp and accurately reflect the implications on the responsibility on the part of companies. Thus, the definition of CSR has evolved and adapted to the context, just as it can be, as we will see, ideological and rooted in different epistemic visions.

Defining CSR

In nearly 100 years of history, there is still no universally or widely accepted definition of the concept; and its many definitions are still a subject of intense debate among scholars. Therefore, CSR must be understood as being not homogeneous, but instead as a landscape of theories rather than an actual comprehensive concept (Garriga et Melé, 2004), with a vast array of definitions, approaches and ways to understand it. That being said, CSR can be generally understood as a guide to how businesses should operate by integrating (and responding to) social values and concerns in their activities. For instance, the European Commission (2011, p. 3) perspective can serve to highlight what is a general (and recent) definition of CSR: "a concept whereby companies integrate social and environmental concerns in their business operations and in their interaction with their stakeholders on a voluntary basis". Overtime many concurrent definitions have been suggested and a myriad of reviews of those definitions have been published. To fully understand the complexity of the concept, these reviews aimed at exploring different aspects of

the concept through: historical perspective (Carroll, 1999; Heald, 1970; Wood, 1991), genealogical approach (Acquier et Aggeri, 2008), conceptual evolution and transition of the concept (Frederick, 1987, 1998; Waddock, 2004), classification of CSR conceptions (Brummer, 1991; Garriga et Melé, 2004; Rahman, 2011) and frequency of use (Dahlsrud, 2008). Notwithstanding this impressive effort of review, McWilliams and colleagues (2006, p. 4) explain the multiplicity of definitions and uses of the concept by the fact that: "the analysis of CSR is still embryonic and thus, theoretical frameworks, measurement, and empirical methods have not yet been resolved." This leads some authors to conclude that CSR has become less an analytic tool than an umbrella construct (den Hond, de Bakker, Neergaard et Gond, 2012; van Oosterhout et Heugens, 2008) under which to understand corporate behaviors and decision-making.

The contested nature of CSR definitions is not a concern for all scholars. Okeye (2009), based on Gallie's theory of *essentially contested concepts*, demonstrated that the dispute of a unique definition of CSR are endless and insoluble by arguments. Okeye concluded that only the need to find a common ground to give sharable meaning and to identify identical subject matter are really of importance, giving scholars flexibility to revisit the definition based on changing contexts and circumstances. Waddock (2004) is not skeptical about the vast array of terminology that is used to describe, in one way or another, CSR. She even goes farther by arguing that the terminologies are not confusing *per see* but rather: "illustrates the very evolution that is of interest in exploring [the concept's] progress, both in practice and in theory" (Waddock, 2004, p. 5). For her and other scholars (Carroll, 1999; Garriga et Melé, 2004), CSR fragmentation is partly attributable to the fact that CSR is often studied through different disciplinary and conceptual lenses, thus requiring adjusting the definition of the concept and refining it contextually to the object being studied.

To better understand the diversity and complexity of the different visions of CSR, and its pertinence to the field of bioethics and application to issues particular to the pharmaceutical sector, some notable examples will be presented. For organisational purposes, their presentation will be divided into three categories based on their scope: 1) profit-oriented, 2) descriptive and procedural, and 3) integrative and normative.

Profit-oriented theories

The narrowest (and older) views of the role of businesses are the ones considering that corporations only have one real duty, so to make profits for their owners. In that sense, some authors only value profit-oriented views of business, such as Dugger (1989) who sees business has a zero-sum game: when some are winning (i.e., the ones who own corporations), then inevitably other will lose (i.e. corporations stakeholders). There is no such thing as a win-win situation or it is only incidental that it will happen. Therefore, for these scholars, being responsible is to make sure that the company fulfills its main duties so to be profitable within the limits of the law.

More nuanced views may agree that social imperatives can be added to the equation. For instance, Jensen (2001), accepts the integration of some social demands if it is profitable in the long-term, as do McWilliams and Siegel (2001) who consider that responding to social demands is "acceptable for the sake of profits". These authors therefore diverge from a strict zero-sum vision (i.e., as soon as someone makes a gain, it is automatically linked to a proportional loss for another), understanding that the value of CSR can be assessed based on corporate financial performance (Garriga et Melé, 2004). Within that view, for a company, even if the very reason for its compliance to CSR will be economical, responding to certain social demands may be reasonable. A study from McKinsey & Company found that institutional investors were ready to pay more than 20% for shares of socially responsible companies and CSR Europe reported 20% of surveyed consumers were ready to pay more for socially and environmentally responsible products (Cheah, Chan et Chieng, 2007). Companies demonstrating socially responsible operations can contribute to financial performance (Baron, 1995; Burke et Logsdon, 1996) and may even be a competitive advantage over competitors who are not demonstrating CSR (Tetrault Sirsly et Lamertz, 2008).

Descriptive and procedural theories

The next step in a more comprehensive vision of CSR is to integrate and value social concerns and demands within its operation. One of the most recognized authors on CSR is Archie Carroll. In a prominent article in 1979, he stated that: "Before anything else, the business institution is the basic economic unit in our society. As such it has a responsibility to produce goods and

services that society wants and to sell them at a profit. All other business roles are predicated on this fundamental assumption." (Carroll, 1979, p. 500) However, according to him, corporate responsibility does not end with economic duties, it is actually rather its beginning.

Therefore, other responsibilities are incumbent to companies: at first, to meet legal duties: "just as society expects business to make a profit (as an incentive and reward) for its efficiency and effectiveness, society expects business to obey the law" (Carroll, 1999, p. 283). Then it is necessary that corporations behave ethically as expected by society. Carroll states that the ethical responsibilities "embody those standards, norms, or expectations that reflect a concern for what consumers, employees, shareholders, and the community regard as fair, just, or in keeping with the respect or protection of stakeholders' moral rights" (Carroll, 1991, p. 41). Finally, contrary to Milton Friedman (1970), Carroll recognizes the importance for a company to comply voluntarily with philanthropic responsibilities, which are the desires that society have toward good corporate citizens (including to actively engage in actions promoting human welfare or goodwill).

To conceptualize these stacking layers of responsibilities, Carroll suggested a four dimensional model embodying the social imperatives that companies must follow, that is "to make a profit, obey the law, be ethical, and be a good corporate citizen" (Carroll, 1991, p. 43). In his pyramidal vision, those four dimensions are hierarchically ordered as the bottom imperatives are more stringent responsibilities than the highest one. Therefore, economic responsibilities form the basis of a corporation's responsibility, followed by legal responsibilities, then comes the ethical responsibilities (obligations to do what is right, just, fair and avoid harms) and at the top of the pyramid lay the philanthropic responsibilities (contribute resources to the community; improve quality of life). In this perspective, the responsibilities are added one after the other and each forms a basic component of the "total" social responsibility of business.

Although Carroll uses the concept of CSR, it is anchored in a performance-oriented vision of companies within society: "with just a slight change of focus, however, we could easily be discussing a [Corporate Social Performance (CSP)] rather than a CSR pyramid" (Carroll, 1991, p. 41), making some authors view his model as more instrumental than normative (Scherer et

Palazzo, 2007; Whetten, Rands et Godfrey, 2002). In order to make CSR more operationalizable, some models have adopted a more procedural perspective. For instance, the "triple bottom line" model have been suggested by consultants as a way that, in addition to financial performance, companies must track, measure and report their social and environmental performance (Acquier et Gond, 2006; Hartman et al., 2014). Those models are not comprehensive as stated by Whetten (2002, p. 384): they "fail to effectively integrate normative perspectives into their descriptive focus".

Integrative and normative theories

In order to be more global, the models must go beyond reporting their performance and incorporate social demands. Models concerned with all the stakeholders of a company thus appeared. One of the most influential models has been the stakeholder approach as suggested by Freeman (1994). Simply put, the theory is opposed to the vision of Friedman, in considering that corporations have responsibility to a wide range of stakeholders, and not only to their shareholders. More comprehensive pyramidal models have also been suggested, such as the one of Otto Lerbinger (2006), which focuses both on maintaining profitability and on functioning as a partner for the community. Lerbinger's pyramidal model is based on five levels (economic function, minimize social costs, help solve social problems, make social investments, and support public policies) that are ranging from "performing its basic economic function to heeding the public interest in the fullest sense" (Lerbinger, 2006, p. 407).

Integrative and normative models recognize the important linkages and interdependence that companies have towards their stakeholders, and society as a whole, as indicated by Tetrault Sirsly and Lamertz (2008): "CSR is intimately tied to a firm's relationships with its stakeholders, indicating that the social obligations of business have specific nonmarket environment beneficiaries whose demands and expectations must be met by firm performance".

According to Scherer and Palazzo (2007), CSR models can be divided in two main categories. On one side, positivist models, such as Carroll's or corporate social performance (CSP), are trying to uncover correlations and causal relationships in the social world by appealing to formal laws inspired by the natural sciences, they thus instrumentalize CSR as another corporate

function. On the other hand, post-positivist models, such as stakeholder theory, base what ought to be done (and avoided) on the social sciences and philosophy (e.g., applied ethics, social contract, critical theory, postmodernism, etc.). While this categorizing can help in mapping the different conceptions of CSR, in the end, as indicated by Garriga and Melé (2004, p. 65): "Integrating empirical and normative aspects of CSR, or economics and ethics, is a great challenge". So regardless of the selected approach, definitions of and debates about CSR remain very complex, and to be clearly understood and be relevant must be adequately operationalized.

CSR in action

What is interesting with CSR is that it is used by academics to understand corporate behaviors as much as it is used in practice and implemented by companies. However, these are also two solitudes that, more often than other, do not talk to each other, to the point where Waddock (2004) considers the academic and practical use of CSR as being in two parallel and distinct universes.

On the academic side, the concept has been used to analyse corporations' impact on an array of specific issues, such as on their employees (Glavas et Kelley, 2014; Marens, 2010, 2013; Odumeru, Ilesanmi, Asabi et Amos, 2014), on managers' attitudes (Hemingway et Maclagan, 2004; Orlitzky, Swanson et Quartermaine, 2006; Quazi, 2003), on developing countries and on globalization (Golli et Yahiaoui, 2009; Jamali et Mirshak, 2006), on the environment (Post, Rahman et Rubow, 2011), on climate change (Stanny et Ely, 2008) and so on. On the other side, in practice, CSR implementation by companies can take multiple forms, but generally it encompasses a strategy using of an array of practical mechanisms. Notwithstanding the actual definition and scope of CSR, here are some examples from the less demanding to the most binding practices that corporations can implement to foster and comply with their CSR.

Values, mission, principles, codes of conduct and codes of ethics. These elements are often general statements that present the philosophy that guides decision-making and conduct of business within the company. Companies will often present these items on their website to publicize the founding elements of their governance and the underlying will for conducting their activities. But having a set of values is not enough, it requires *organizational authenticity* in

order to commit to the values and to nourish an organizational culture fostering values and their actual realization (Auster et Freeman, 2012).

Monitoring, benchmarking and reporting CSR compliance and impacts. Many companies go beyond the philosophical statement and are committed to demonstrating their adherence to their values by reporting their initiatives, activities and decisions taken to foster their CSR and, sometimes, even by measuring their impact. This can take the form of annual or *ad hoc* reports – on topics like economics, social and environmental impacts as well as impacts on their employees and certain stakeholders – to be submitted to their shareholders and, more broadly, to the public. In addition to stemming from companies' goodwill (being voluntary), this is a way for companies to comply with increasing requirements regarding the transparency of their conduct. Such reports also serve companies as a way to distinguish themselves from competitors, not only by their products or services, but by their CSR commitment and accomplishments. For instance, Esrock and Leichty (1998) reported that even back in 1998, 82% of Fortune 500's companies reported CSR on their website. Therefore reporting corporate compliance is a key asset of corporate communication, which is now vital due to the growing importance of how corporations are perceived by their stakeholders (Cornelissen, 2014). However, it is often criticized as being a mere way to legitimize current business practices by CEOs: too often they serve as *post-hoc* rationalization and rhetoric for what have been done throughout the year (Barkemeyer, Comyns, Figge et Napolitano, 2014).

Initiatives and demonstrations of company CSR. Companies seeking to go beyond simply reporting of their compliance toward CSR, may engage in socially-oriented activities in line with their business sector. This can take the form of commitment to greener practices (which provide, according to Russo and Fouts (1997), increased firm-specific benefits), as this may be a response to a problem that the company considers to be socially significant (e.g., Starbucks forbidding customers from wearing guns in their coffee shops) (L. J. Collins, 2014; Morsing et Roepstorff, 2014) or to a tragedy striking its commercial sector (e.g., following the Rana Plaza tragedy in Bangladesh in 2013, where 1,129 employees died in the collapse of the factory, a consortium of companies signed an engagement toward security and more responsible practices) (Reinecke et Donaghey, 2015; Solaiman, 2013). Some companies are pushing their commitment

to contribute to a more equitable society even further and have implanted more radical means to achieve this. For instance, the CEO of Gravity Payments, a credit-card processing company, voluntarily reduced his own salary by 93% in order that all 70 employees could receive a minimal salary of $70,000 per year (MacDonald, 2015); so an increase of nearly two-fold the average salary within the company, far higher than the federal minimal wage of $7.25 per hour. In light of these examples, it is easy to understand why Tetrault Sirsly and Lamertz (2008) state that CSR initiatives can be viewed as leverages that are "rare, valuable, and costly to imitate" providing first-mover advantages and competitive gains. The benefits of these kinds of initiatives can provide: "both tangible economic gains in market share and cost savings as well as intangible, but nonetheless valuable, enhancements to reputation and social legitimacy" (Tetrault Sirsly et Lamertz, 2008, p. 365).

Integrative CSR management and partnerships. Making the leap from a CSR initiative to incorporating CSR management in all the activities of a company is complex and very demanding. However, successful implementation of corporate social responsibility requires that the leadership of the corporation is willing, competent and ready to become a key asset of CSR management both within and outside the corporation (Jacobson, Hood et Van Buren, 2014). Integrative CSR management also entails the establishment of partnerships as ways of engaging various stakeholders around a common objective (Lerga, 2009); this is challenging since it requires trust and accountability, openness to evidence and new knowledge, and cooperation with multiple actors of different sectors.

Engaging in political CSR with key actors. The successful implementation of corporate social responsibility requires, according to Lerga (2009), the transformation (at least minimally) of the whole society. To achieve this, the business sector, as a key player in corporate social responsibility, must coordinate and work with the full spectrum of its stakeholders (other business organizations, educational institutions, professional associations, the media, government and non-governmental organizations). Some companies have committed (at the very least, at various levels) to such a transformation. For instance, during the Winter Olympics in Russia in 2014, Google demonstrated explicit support for gays, lesbians and transgender employees and homosexual marriage in a campaign for human rights and inclusion and worked

with numerous stakeholders in order to bring a change in the Russian society (Morsing et Roepstorff, 2014). While very demanding for companies, the fact remains that the next major development of CSR will be the political role of companies, which to date has not been sufficiently taken into account, nor well assume by corporations (Scherer et Palazzo, 2007).

Skepticism about CSR

Even if models and frameworks have been developed to better understand corporations' social impacts and responsibilities, and for managers to better conduct their operations, as Waddock notes, "good corporate citizenship/good management practice is hardly rocket science" (Waddock, 2004, p. 7).

Obviously, being contingent to the complexity of the constraints and divergent imperatives, necessitating reflexivity about how best to balance social demands and the appropriate response that a company should have, good corporate management will never be as precise as rocket science (nor would one expect other forms of applied ethics be more accurate and infallible). Skepticism can also come from practical considerations, such as Banerjee (2001, p. 42), who considers that CSR is "too broad in its scope to be relevant to organizations" or Scherer and Palazzo (2011) who hold that literature of CSR theorizing has not yet sufficiently integrated the political role of private business. Others study the instrumentalization of CSR from the perspective of Chief Executive Officers and other organizational leaders in search of legitimacy using CSR as a rhetoric (Barkemeyer et al., 2014; Marais, 2012) or on consumers' skepticism about the integrity and validity of CSR campaigns (Theofilou et Jerofejeva, 2010). The epistemological position on business ethics can also cause skepticism. For instance, Jones et al (2005, p. 173) consider that given the "very multiplicity of ideas about human nature, progress, utopia, beauty and so on" it is rather difficult to expect that *ethics* can articulate a "good that is self-evident from a first or universal principle" and that could be used to evaluate corporate conduct. These perspectives show an enduring skepticism that a corporation can fulfill stakeholders' expectations of such a scattered concept as CSR.

In the end, what truly affects CSR implementation within a company and what can affect managers' room for maneuver in considering social demands holds essentially on two things:

1) the very origin of the motivation for a company in venturing into CSR compliance (is it a top-down decision that may be more instrumental, or does it come from corporate culture and a concrete need and a willingness to take the means to achieve it?); which directly affects 2) the vision of CSR that will be adopted (descriptive or normative). Thus according to (Acquier et Gond, 2006, p. 84), there is still much to be done to refine the concept and its use: "The challenge is to move from a theoretical approach of CSR largely dominated by a structural-functionalist perspective to research recognizing the subjective, dynamic and socially constructed nature of the concept, so as to register it in a post-positivist perspective." (Translation by author)

Discussion

While business ethics as a field has gone, in the last decade, from "whether" to use CSR to "how" to do so (Du, Bhattacharya et Sen, 2007), bioethics, I suggest, should learn from this and build on the reflection, and therefore take an interest in "how" this concept can be incorporated in its tools and even, *a fortiori*, in its epistemology. Obviously, the object of study of bioethics and CSR are very different, but that does not mean that the gap cannot be bridged or that there is no interest in doing so. To achieve this bridging or integration, it is important to reflect on four major themes: the epistemic foundations of bioethics and CSR, their possible of overlap, their origins and what bioethics can learn from skepticism about CSR.

The benefits of having a joint vision of business and health-related activities

Both the normative way they look at certain practices and the fact that both stem from a need to reflect on and to police morally questionable practices (either in the business environment or in healthcare/research) highlight the relevance of using a dual lens – CSR and bioethics – to be normative about health-related business activities and concerns. As CSR is generally concerned with treating company's stakeholders in a manner deemed acceptable in a society, there are no macro models in bioethics shedding light on how to understand the corporate social role and how manager can (and should) meet their social obligations. The variety of stakeholders must be taken into account. Even in a business context related to life sciences (where the most easily identifiable stakeholders would be the patients, health professionals, regulatory agencies, etc.), it is important to recognize the importance that companies need also to consider their employees, and a plethora of other stakeholders (such as, employees' family, suppliers, the environment,

etc.), which increases burden of the social obligations of companies. This kind of consideration is generally ignored in bioethics. Thus, the very concept of responsibility in CSR goes beyond a bioethical perspective, opening at the same time the possibility of and need to recognize and to better define corporate responsibility in bioethics. Much like for any other issues in bioethics, a pluralistic (and interdisciplinary) perspective may help to resolve bioethical dilemmas.

Avoiding harm as a starting point of overlap

Enshrined in both bioethics and CSR isthe overarching notion of harm; more specifically, to avoid harm, notably in the form of consumer protection or patient protection against harm. This notion is transversal to bioethics, where the reduction of harms is essential (either to individuals, communities or to society). For its part, the notion of harm is related to CSR core which is the responsibility of individuals and organizations. This responsibility, according to Hartman et al (2014), is generally defined through three different levels of responsibility. In a scale ranging from the less binding to the more demanding, there would be the responsibility: 1) not to cause harm, 2) to prevent harm; and 3) to do good. Thus, at the very foundation of CSR lies the notion of harm. The vocabulary of *harm* and *good* demonstrates the fact that there is a semantic gradation in CSR in the sense that the conception of responsibility stands on a spectrum where on one end it is sufficient to avoid harm, while on the other end one ought to proactively seek to do good.

This shows that there is an interesting difference between the vision of bioethics and CSR about the notion of harm. The nature of harms has an impact on accountability assessment and what ought to be done. For CSR, harms can be economic, social, cultural, environmental as well as health-related. However, in bioethics, harms are mostly health-related, affecting the dignity of persons, and somewhat irrevocable; harms can also include a multiplicity of other dimensions, such as economic, but preference is often given to health-related concerns. It is perhaps in this sense that CSR is often considered by companies as not very demanding and so rather easy to comply with (harm minimization being sufficient), while any other obligation (harm prevention and doing good) is seen as supererogatory. Harm avoidance as a common ground can serve as a starting point to the overlap of both ethical lenses, other concepts can help extend their overlap. Returning on the case of drug promotion, it is possible to see that other bioethical concepts

emerge in reflections on CSR. It has been possible to easily see an intersection between bioethics and CSR, as van de Pol and de Bakker (2010) analyzed the latter through protection of consumer autonomy and the need to avoid harm. These two concerns can easily be transferred in bioethics. Thus, at the interface between the two lies the same core concerns. Of course, it is only a case study meaning that it is not possible to generalize this interface, moreover as the overarching concerns of profitability did not entered in the authors' analysis. But it is also a respond to skepticism that CSR has only profit-making pursuit and protect as its main bottom line. van de Pol and de Bakker stress on the importance that corporations assume their responsibility by being consistent with their social environment and their stakeholders.

A CSR approach can be instrumental in understanding that companies, to be responsible, need to respond to societal concerns, and how feasible and challenging this can be. Beyond the simple assertion that the value of life and the dignity of patients must be preponderant (as required from a bioethical perspective), in a competitive business environment profits and sustainability may be the key elements, alongside various social concerns. There is thus a certain dichotomy between what is valued as being cardinal for guiding the normative gaze. As we saw with DTCA, those social concerns are not univocal; scholars, policy-makers, physicians, pharmacists and patients do not agree on what is best (i.e., whether DTCA improves or dampen patients' autonomy), nor do distinct jurisdictions have the same views. Incorporating CSR provides nuances to bioethics, widening concerns, in a corporate setting, about what is important for different actors, thus leading to a much more detailed view of responsibility.

Conclusion

Corporate social responsibility has been extensively discussed both in the scientific literature as among business practitioners and, interestingly enough, its history is even longer than that of bioethics. Although never having reached the point of standardization, this "umbrella of constructs" still can serve in understanding corporate behaviors and decision-making. Therefore, it is interesting to ponder what bioethics can learn from CSR and how to reconcile their episteme. The first thing that stands out is the fact that their object of study is different. CSR is interested in companies' behaviors as bioethics is interested in health-related issues, but both deal with the ethical concerns affecting a wide range of stakeholders. Second, responsibility

is not fully understood in the same way, the minimum requirements are not placed on the same level, and may even have different spectrum to understand and balance competing ethical imperatives. Third, combining CSR to bioethics clearly help better assessing the complexity of business activities and of health-related concerns. Notwithstanding these considerations, as long as CSR is not conducted following a genuine motivation and may seem to be instrumentalized, skepticism will justifiably remain. This is exemplified by a vision such as that of Borch-Jacobsen who only sees CSR as an instrumental tool for companies who are adding "as a zest of "social responsibility" in their marketing mixture" (Borch-Jacobsen, 2014, p. 75). To answer such criticisms, it is important that a pharmaceutical company acknowledge that it has a distinct role to play (and has resulting special responsibilities), that is different from any other type of industry, since human health is much more complex and sensitive than the sale of commodities.

CSR is an interesting avenue, though it is not a panacea and the very notion of social demand will remain difficult to reconcile, as stated by Welcomer (2002, p. 251):

> Although laws and regulations have delineated specific standards for compliance with societal expectations, voluntary compliance with societal expectations is an enigmatic phenomenon. Predicated on the unstable ground of ethical and instrumental rationales, the mechanisms that compel the firm to consider societal interests are not well understood.

This leads to realize that bioethics is not better equipped. Quite the contrary, bioethics has an interest to adopt a more comprehensive vision in order to be able to better understand how to integrate normative stakeholders demands for prosocial corporate behavior and how company can willingly comply, beyond legalistic requirements (Hahn, 2015). Although, there is not a univocal way to define CSR, the polysemic nature of the concept can illuminate and help to better contextualize bioethical issues where commercial practices and human health intersect. For example, a simple model like Carroll's can help for understanding the hierarchy of imperatives motivating the conduct of business. This model remains simple and based on a continuum of responsibility different than the one of bioethics (being much less demanding than bioethics would probably expect), but would still allow a more informed perspective on an issue involving interests of profitability, for which bioethics is not particularly well equipped.

A discussion on CSR also enables one to see that companies already bear an ethical perspective on their practices, are evaluated and evaluate themselves based on the achievement of certain ethical standards. However, these standards and evaluation mechanisms are different from those of bioethics, among other things due to differences in their episteme, leading to a different understanding of the very notion of responsibility. In this sense, bioethics has something to learn from CSR and should invest more in exploring commercial practices to better grasp and have a say on how companies are judged and evaluated, such as on the sustainability of their practice. That being said, there is a certain responsiveness and a need on the part of the CSR to be analyzed and re-appropriated by bioethics; as stated by McWilliams and colleagues (2006), the concept "cannot be analyzed through the lens of a single disciplinary perspective. Thus, it appears that CSR is fertile ground for theory development and empirical analysis." Thus, a reappropriation of the concept, in bioethics, is all the more important that it is seen as desirable to use the concept in an interdisciplinary context, what is, in essence, bioethics. This is important because bioethics will never cease to need more tools helping to better understand the complexity and ramifications of health cares and of living conditions improvements.

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Mieux comprendre les comportements des joueurs pour mieux conceptualiser les repères éthiques et baliser les règles du jeu

Bien que le concept de responsabilité sociale des entreprises n'a que très peu percolé en bioéthique, il a le potentiel d'apporter des outils conceptuels permettant de mieux prendre en compte les dimensions commerciales sous-jacentes aux enjeux bioéthiques. La RSE demeure un des cadres conceptuels les plus utilisés, tant en éthique des affaires que par les compagnies pharmaceutiques elles-mêmes, et donc représente une avenue intéressante pour arriver à établir de meilleurs ponts et un langage commun entre les bioéthiciens et les employés de l'industrie. Cela ne veut pas dire que le concept à lui seul doive être considéré comme l'unique voie à l'implantation de ce dialogue, il peut toutefois servir de guide aux pratiques de l'industrie et à les arrimer aux attentes pro-sociales des divers acteurs (consommateurs, régulateurs, etc.). Cette nécessité pour la bioéthique d'avoir la capacité, au sein même de son éthos et de ses outils analytiques et réflexifs, d'apprécier l'importance que peut avoir la dimension commerciale passe par un élargissement des considérations jugées éthiquement pertinentes. D'où l'intérêt de penser une bioéthique pharmaceutique capable d'apprécier les dimensions particulières de cette industrie et de conceptualiser une éthique du marketing pharmaceutique.

Une telle démarche permettrait une énonciation des standards éthiques de sorte à rendre plus attrayantes certaines pratiques, qui seront perçues comme étant plus acceptables et justifiant l'alignement de la rentabilité recherchée aux attentes pro-sociales. La RSE permet de donner un sens et de valoriser les impératifs pro-sociaux au sein du modèle d'affaires et des pratiques d'une entreprise où l'économique prime. Au sein de la bioéthique, c'est le chemin inverse qui doit être fait, c'est-à-dire faire reconnaître l'importance de la dimension commerciale comme étant une condition *sine qua non* pour les entreprises et dans cette optique aligner les pratiques aux impératifs bioéthiques.

L'objectif de la thèse, tout comme la question de recherche proposée, est double : établir les repères (bio)éthiques qui doivent guider l'hétérorégulation et l'autorégulation de l'industrie en matière de CDCM ainsi que d'énoncer comment la bioéthique peut soutenir les employés l'industrie dans la conduite de leurs activités promotionnelles. Pour ce faire, il est important de s'intéresser aux pratiques de l'industrie en matière de marketing direct aux consommateurs à

travers une démarche qui, à la fois, fait l'analyse des responsabilités des acteurs tout en cherchant à établir les repères éthiques qui doivent guider les pratiques basées sur des cas réels. Dans un premier temps (Partie II), il convient de s'intéresser à l'hétérorégulation provenant des agences règlementaires, comme balise pour l'établissement des « règles du jeu » qui devront être suivi par l'industrie, pour ensuite (Partie III) aborder la question de l'autorégulation des pratiques commerciales et aux modalités à travers lesquels une bioéthique pharmaceutique peut venir en soutien aux employés en vue de rendre plus éthiques les pratiques de marketing pharmaceutique.

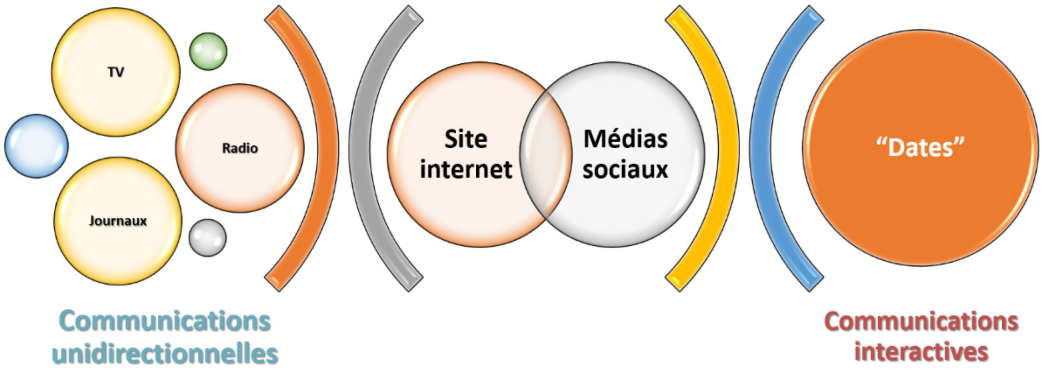
Partie II – Analyse par études de cas

Après avoir approfondi les enjeux éthiques et régulatoires découlant de l'encadrement et des pratiques de CDCM ainsi que les outils conceptuels qui pourraient permettre un regard normatif plus efficace et adéquat pour la bioéthique, l'analyse se concentrera sur l'hétérorégulation des pratiques de CDCM. Pour parvenir à dégager et analyser les principaux enjeux éthiques qui découlent de la règlementation actuelle à laquelle est soumise l'industrie dans ses pratiques de communications directes aux consommateurs, est déployée une approche méthodologique permettant d'apprécier les grandes tendances et mettre l'emphase sur certaines considérations règlementaires, politiques, sociales et éthiques. C'est par l'étude de cas exemplifiant la diversité des pratiques marketing que seront explicités les enjeux éthiques et régulatoires des CDCM. Le but est de cibler l'hétérorégulation des différentes déclinaisons de CDCM en brossant le portrait des grands enjeux éthiques qui découlent de l'état actuel des lois, de la règlementation et des mécanismes de surveillance. L'hétérorégulation est vue comme formant les « règles du jeu » à travers lesquels les compagnies naviguent et qui facilitent, légitiment ou interdisent certaines pratiques.

L'échantillonnage des cas s'est fait de façon instrumentale (Stake, 2005), c'est-à-dire que les cas ont été choisis pour leur pertinence et leur caractère exemplatif permettant de « [mettre] l'accent sur une question ou une préoccupation [en choisissant] un cas pour illustrer cette préoccupation » (M.-F. Fortin, 2010, p. 279). Cet échantillon raisonné permet de traiter, dans le cadre d'une analyse spécifique (Yin, 2003), chacune des grandes familles de CDCM, tel que conceptualisées dans le continuum des CDCM (voir Figure 8). Les cas présentés n'ont pas la prétention d'être exhaustifs et d'épuiser l'ensemble des enjeux éthiques que peuvent poser les CDCM. Chaque cas fut sélectionné en fonction de son exemplarité, de son caractère de représentativité de chacun des types de communications et de sa capacité à offrir un sommaire des principales dimensions particulières de ces CDCM. Ils couvrent ainsi l'impact sur l'autonomie et la structuration des choix des consommateurs, le rôle des régulateurs et leur efficacité à baliser les règles établissant les pratiques acceptables et la légitimité des interactions industrie/consommateurs à très grande proximité et non médiés. Les cas sont basés sur une revue

non systématique de la littérature et les sources ont été choisies sur la base de leur apport à détailler chacun des cas et à rendre compte des principales analyses et critiques. La contextualisation de chacun des cas sert de matière pour l'analyse conceptuelle et normative. L'objectif, dans le cadre de chaque cas et de façon plus générale celui de la thèse, est d'émettre des recommandations quant à la responsabilité des principaux acteurs (gouvernements et industrie) en vue de mieux encadrer la pratique marketing en balisant l'éthique des CDCM.

Figure 8. Continuum des types de communications directes aux consommateurs



Cadre de référence pour les études de cas

L'étude d'un cas par dispositif de communication permet de porter un regard analytique et normatif sur l'ensemble des pratiques de marketing destinées aux consommateurs. Pour ce faire, il est possible de classer la multiplicité des dispositifs marketing pour rejoindre directement les consommateurs sous forme d'un continuum (voir Figure 8). Le continuum permet de représenter l'ensemble des outils promotionnels dont disposent les compagnies pharmaceutiques pour rejoindre directement les consommateurs et sert à la : « coordination of all seller initiated efforts to set up channels of information and persuasion in order to sell goods and services or promote an idea » (Belch et Belch, 2008, p. 16). Chacun de ces types de communication sert à promouvoir l'idée qu'un certain médicament saura répondre aux besoins des consommateurs afin de les persuader de se procurer le produit (ou la gamme de produits) promu, généralement en les encourageant à parler à leur médecin.

Le continuum distingue les types de DTCC selon leur degré de proximité et leur niveau potentiel d'interactions avec les consommateurs. Ainsi, sur l'axe sont représentés, à gauche, les dispositifs visant à rejoindre une grande population par des messages unidirectionnels où le consommateur est passif. Ces communications passent par les médias de masse – télévision, radio et périodiques – ce qui permet de rejoindre un auditoire très varié et assez représentatif de l'ensemble de la population. La proximité entre la compagnie et les consommateurs est très faible au sens où il n'existe pas d'interface directe (soit un dispositif permettant l'échange d'information, comme le permet le web) entre le destinateur (le fabricant du produit) et les destinataires (les consommateurs). Ainsi, les médias (télévision, radio, périodiques) ne permettent pas au destinataire de la communication d'interagir avec le destinateur ni directement avec amis, famille, connaissances, etc.

Au centre, se trouvent les communications interactives que permettent les médias électroniques. D'un côté, le web 1.0 permet de rejoindre les consommateurs, soit à travers de pages officielles dédiées à faire la promotion d'un produit en particulier, ou d'une gamme de produits, ou à travers des pages web visant la sensibilisation des patients à une condition particulière. Cela exclut les pages officielles des compagnies qui présentent leurs activités, leur mission et leur gamme de produits[17] ainsi que les sites des communautés de patients,[18] ces pages peuvent avoir un rôle, mais ne sont pas à proprement parler des dispositifs de communications directes aux consommateurs. De l'autre côté, le web 2.0 a permis d'accroître, de façon exponentielle, les possibilités d'interaction entre utilisateurs grâce aux médias sociaux, c'est-à-dire Facebook, Twitter, Instagram, Google +, etc. Les compagnies peuvent ainsi interagir plus facilement avec des auditoires plus spécifiques et potentiellement réceptifs à leurs produits. Cette sélection est possible (contrairement aux médias de masse) en segmentant les utilisateurs selon les informations collectées par les plateformes d'échange. L'avantage de ces plateformes est que la

[17] Ces pages ont comme fonction première de contribuer à l'image de marque de la compagnie plutôt que comme vecteur promotionnel.

[18] À titre d'exemple, le site PatientsLikeMe (https://www.patientslikeme.com/) est une plateforme en ligne d'échange d'informations permettant aux patients de diffuser et de discuter de leur condition, de leurs symptômes, de leur historique médical, des traitements qu'ils ont reçus, des effets indésirables qu'ils ont ressentis, de leur qualité de vie et de la progression de leur état de santé. Créée en 2004, la communauté d'utilisateurs dépasse maintenant le demi-million. Bien que l'industrie pharmaceutique ait des liens étroits avec la plateforme, cela ne sert pas à proprement parler de véhicule promotionnel quoique leur présence renforce la pharmaceuticalisation du soin et du traitement des patients.

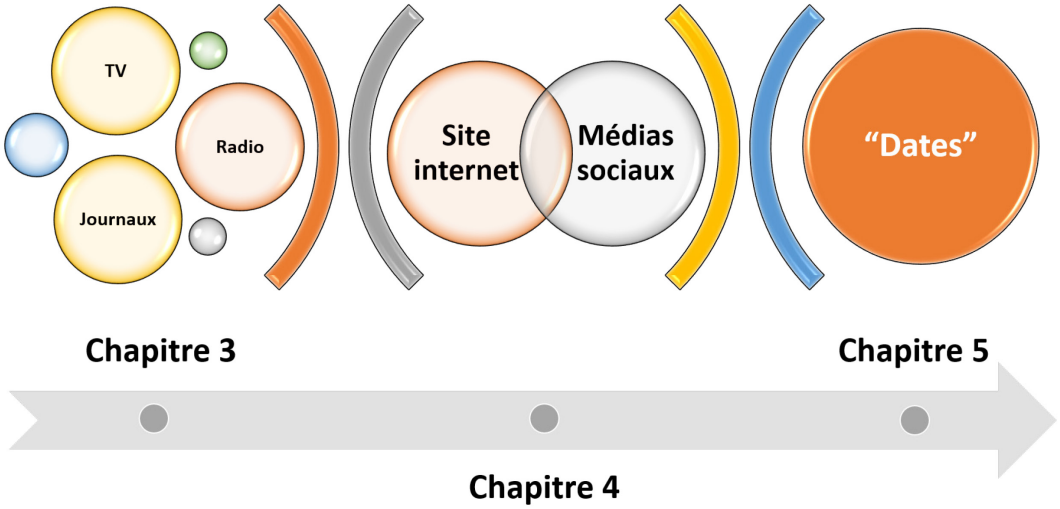
population rejointe, tout en étant substantielle et transfrontalière, est au centre d'échanges qui peuvent être, à la fois, bidirectionnels (entre destinateur et destinataires), mais également générateurs de discussions entre consommateurs. La proximité étant donc grande tout en conservant une interface (la plateforme électronique) permettant une distanciation entre l'utilisateur et le promoteur du message.

À droite de l'axe, se trouvent les interactions directes en présentiel que peuvent avoir des représentants de l'industrie avec des consommateurs. La proximité est donc maximale puisque les interactions ont lieu en personne – par des employés, représentants pharmaceutiques ou professionnels de la santé et scientifiques rémunérés par une compagnie – directement avec des consommateurs. Objectif ultime du marketing, car il permet une interactivité inégalée et permet de s'adresser à des consommateurs identifiés comme ayant le plus grand potentiel d'effet d'entraînement au niveau des ventes.

Inscrit à même le continuum, il y a cette idée de la progression[19] du marketing pharmaceutique qui s'est fait d'abord fait auprès des masses de consommateurs pour inclure de plus en plus des formes d'interactions avec les consommateurs. Ces développements sont en phase avec l'évolution même de la philosophie et des pratiques marketing qui, selon Lusch (2007, p. 267): « [are] moving away from a market(ing)-*to* philosophy and practice and toward a market(ing)-*with* philosophy and practice » (emphase ajoutée). Les modalités pour rejoindre les consommateurs sont donc multiples cependant, comme il a été souligné précédemment, la gamme d'interactions directes avec le consommateur varie selon la juridiction où évolue l'entreprise. Certains dispositifs peuvent être encadrés, limités ou même interdits selon le type de règlementation en vigueur. Bien que la plupart de ces dispositifs soient des améliorations sur le plan communicationnel, ils sont générateurs également autant d'enjeux commerciaux et éthiques auxquels doivent faire face les acteurs du secteur pharmaceutique.

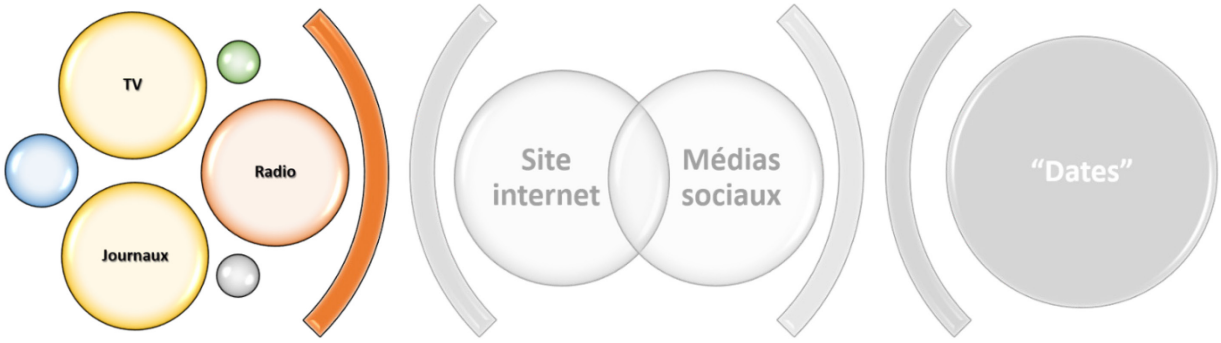
[19] En termes de développement, l'idée n'est pas ici de qualifier si les nouveaux dispositifs représentent en soi un progrès pour les consommateurs.

Figure 9. Place des chapitres dans le continuum des types de communications directes aux consommateurs



Les trois prochains chapitres sont structurés suivant le continuum des types de communications directes aux consommateurs (voir Figure 9) et chercherons à porter un regard normatif sur l'hétérorégulation des CDCM. D'abord, le **Chapitre 3** porte sur les communications utilisant des médias de masse en traitant, notamment, des impacts de la rhétorique promotionnelle sur l'autonomie des consommateurs. Ensuite, le **Chapitre 4** se concentre sur les sites internet et les médias sociaux et traitera notamment du concept de familiarisation et de la clarification du rôle des régulateurs, comme devant établir les règles du jeu, pour baliser les pratiques (dont l'autorégulation) de l'industrie. Finalement, le **Chapitre 5** cible les interactions en présentiel entre représentants de l'industrie et consommateurs. La réflexion portera sur la pertinence et la légitimité de l'industrie à informer les consommateurs dans un cadre aussi interactif et sans qu'il y ait d'intermédiaires indépendants.

Chapitre 3 – La communication à travers les médias traditionnels



Le premier dispositif à l'étude constitue celui qui permet de rejoindre de larges pans de la population par des messages utilisant les médias de masse traditionnels : télévision, radio et médias imprimés (journaux, magazines, revues). Bien que ce type de dispositif n'ait pas les avantages d'interactivité et de segmentation qu'offrent les médias électroniques, ce type de communications représente encore aujourd'hui la part du lion en termes de dépenses en CDCM, notamment par leurs coûts élevés, que l'on justifie par la possibilité de rejoindre un auditoire très varié et assez représentatif de l'ensemble de la population.

Le chapitre est constitué de l'article « *Menstrual Suppression Advertisements: How Does a Rhetoric of Choice Affect Reproductive Autonomy?* », soumis au *Journal of Medical Ethics*. Le cas à l'étude porte sur la publicité directe des médicaments (DTCA) visant la suppression des menstruations, grâce à des contraceptifs hormonaux, ayant lieu principalement aux États-Unis. Qualifié de médicament de style de vie, il est largement prescrit pour des raisons de convenance plutôt qu'une nécessité médicale. L'article s'intéresse à la rhétorique marketing présente dans les communications auprès des consommatrices qui met justement l'emphase sur les dimensions de choix, de libération, de convenance et une certaine vision de l'autonomie. L'article présente un bref historique de la montée en popularité de la suppression des menstruations dans les médias populaires ainsi des communications promotionnelles auprès des femmes et de leurs médecins. Ensuite, est analysé le discours promotionnel ainsi que ses effets sur les choix et les représentations faites sur les menstruations. Puis, est discutée, l'attention particulière qui est requise de la part des régulateurs lors de la surveillance et l'évaluation des messages

promotionnels pour des médicaments sur le mode de vie, tels que les contraceptifs hormonaux pour la suppression des menstruations, afin de s'assurer que ces messages informent adéquatement les femmes des conséquences de l'utilisation du médicament. Est également défendu le fait que l'autonomie des femmes n'est pas bien servie en permettant l'utilisation d'une rhétorique trompeuse mettant l'emphase sur les notions de choix et de convenance.

J'ai écrit le premier brouillon de l'article. Vardit Ravistky, Victoria Doudenkova et Bryn Williams-Jones ont ensuite tour à tour commenté l'article en ajoutant des informations et des idées pour renforcer l'argumentation et la logique du texte. J'ai révisé chacune des nouvelles versions et tous se sont entendus sur la version à soumettre à la revue. La distribution et l'ordre de l'autorat ont été discutés et décidés de façon consensuelle. L'article a depuis fait l'objet d'une présentation à la 23e conférence de la Société canadienne de bioéthique.

Menstrual Suppression Advertisements: Rhetoric of Choice and Women's Autonomy

Bélisle-Pipon, J.-C.; Ravitsky, V.; Doudenkova, V. & Williams-Jones, B. Menstrual Suppression Advertisements: Rhetoric of Choice and Women's Autonomy. Soumis à *HEC Forum*.

Abstract

Commercialized for over half a century, hormonal contraceptive drugs (HCD) are now ubiquitous in Western countries. In addition to their effect on women's emancipation and reproductive autonomy, their success is partly due to pharmaceutical company advertising emphasising non-contraceptive dimensions pertaining to women's lifestyles. Initially advertised in North America as a way to treat severe acne and premenstrual dysphoric disorder, and to permit menstruation frequency reduction, since 2003 extended HCD regime (eHCDr) have been marketed as a means of complete menstrual suppression. These advertisements promote the positive value of controlling menstrual cycles while downplaying the drugs' adverse effects and even trivializing their use. Paradoxically, HCD was initially framed as liberating women by giving them control over their reproduction. But in downplaying the problems associated with the return of fertility and the masking of underlying fertility problems, eHCDr may in fact reduce a woman's capacity to make informed decisions about when to conceive, thereby significantly restricting her reproductive autonomy. This article focuses on the impact of eHCDr drug promotion on women's autonomy, both with regards to control of their daily lives and their reproduction. We reject the framing of women's autonomy in drug promotion as simply a matter of "lifestyle choice", and argue for a more critical understanding of the social and cultural factors (expectations, pressures, social constructs) that frame womanhood and informed choices with a rather limited view of women's autonomy.

Keywords: choice, direct-to-consumer, extended regime, hormonal contraceptive drugs, lifestyle drug, marketing, menstrual suppression, reproductive autonomy, women's autonomy

Introduction

Commercialized for more than half a century, hormonal contraceptive drugs (HCD) are now ubiquitous in most Western countries (Junod et Marks, 2002). In addition to their effect on women's emancipation and reproductive autonomy, the success of "the pill" is partly due to

advertising efforts by pharmaceutical companies that emphasize lifestyle dimensions beyond contraception (Kissling, 2013; Medley-Rath et Simonds, 2010; Smith, 2014) The positive side effects of HCD—such as for the treatment of severe acne or premenstrual dysphoric disorder, and the reduction of menstruation frequency—led to the subsequent marketing of these "added benefits" (Watkins, 2012). In 2003, with the approval of Seasonale® in the United States, cycle-stopping HCD started to be marketed as a means for women to achieve menstrual suppression (MS). Women now have access to products inducing MS either as a desired side effect of contraceptives, through progestin delivery systems (such as the injectable Depo Provera® and the intrauterine device Mirena®) or as an official primary indication for continuous combined oral contraceptives (such as Seasonale®/Seasonique® and Lybrel™). These "extended HCD regimen" (eHCDr) products interfere with hormonal mechanisms and prevent menstrual flow. In comparison with traditional oral contraceptives, which mimic a woman's natural cycle using a combination of active pills and placebos following a 21/7 regimen,[20] eHCDr extend the continuous action of hormones to block the regular hormonal cycle. For instance, Seasonale works on an 84/7 regimen (three months of active pills instead of three weeks). Women taking this drug experience four withdrawal bleedings annually instead of 12. Lybrel™, launched in 2007, consists of 365 active pills without any placebo, and is designed to completely eliminate a woman's monthly bleeding. In one form or another, eHCDr are all menstrual suppressors.

With the advent of eHCDr, the language of "choice" initially associated with HCD regarding when to procreate has been replaced by "the convenience" of living without menstruations. In promotional messages and in the popular media, the benefits of these drugs are often overrepresented in comparison with their potentially serious adverse effects (Johnston-Robledo, Barnack et Wares, 2006; Till, 2015). In this article, we build upon the work of scholars[21] who have analyzed the pervasive rhetoric of choice and the implicit attempt to control women in MS promotional messages to argue that MS advertising undermines the free exercise of women's

[20] A 21/7 regimen means that a woman will take 21 active pills followed by 7 placebos that cause monthly withdrawal bleeding (a so-called period, that differs from regular menstruations). Interestingly, the choice of a 21/7 regimen was not for safety or efficacy concerns, but rather to provide the appearance of the body's natural rhythm and so make the technology more socially acceptable (Hillard, 2014).

[21] Such as Carly Woods, Melissa Nader, Elizabeth Kissling, Ingrid Johnston-Robledo, and Kara Granzow (Granzow, 2007; Johnston-Robledo, Barnack et Wares, 2006; Kissling, 2013; Nader, 2007; Woods, 2013).

autonomy. While direct-to-consumer communications (DTCC) are usually justified by proponents on the grounds that they provide relevant and unbiased information to promote consumers' informed choice and autonomy (Gilbody et al., 2005; M. Harker et Harker, 2007), promotion of MS does exactly the opposite.

To lay the groundwork, we begin with a brief history of the rise of MS in the popular media and in promotional communications to women and their healthcare providers. This is followed by a presentation of the clinical facts relating to MS, with particular attention to the reversibility effect, i.e., the delay in fertility return in women ceasing their use of eHCDrs, and the corresponding need for long-term studies on the effects of these drugs on women's fertility in general. With this information in hand, we then analyse MS drug promotion discourse, its framing effect on choice, and the related consequences for autonomy. More specifically, we argue that a more nuanced view of informed choice that pays attention to the social construction of womanhood (conveyed by these advertisements) can provide important insights into the pernicious consequences of MS promotion. Such insight can support the development of recommendations to improve drug regulation. Notably, caution is required on the part of regulators when approving promotional messages for lifestyle drugs, such as HCD for MS, to ensure that such messages adequately inform women about the consequences of using the medication. We argue that women's (reproductive) autonomy is not well served by permitting the use of a misleading rhetoric of choice.

Promotional Activities and Their influence on choice

Drug advertisements have played an important role in popularizing the use of contraceptives since their commercialization in the late 1950s and early 1960s, despite the censorship imposed on advertising and the restrictions on access to HCD products in some countries (Bailey, 2010). At first, ads were only addressed to physicians through medical journals to raise awareness about the advent of contraceptives. The emphasis was on the liberation of women from their own biological functions and the appropriation of control over their bodies. For instance, the very first HCD, Enovid, was advertised as "the first fully feminine molecule for cyclic control of ovulation" (« Enovid® », 1962). Following the relaxation of drug promotion regulations, particularly in the US, companies began to directly target women (Watkins, 2012). This

coincided with a shift in advertising campaigns: between the 1960s and 1980s, HCD promotion focused on birth control and family planning, but starting in the 1990s, the focus shifted to lifestyle benefits.

Innovation in the area of HCD has largely been limited to its marketing (Watkins, 2012). The basic science behind the "pill" is more than half a century old, but while manufacturers have been advertising their drugs as being cutting-edge and truly innovative, very little has changed besides how the drugs are marketed: "Marketing decisions, rather than scientific innovations, have guided the development and positioning of next-generation contraceptive products in recent years." (Watkins, 2012, p. 1463-1464) Watkins goes further by arguing that MS is one of three tactics used by manufacturers to revamp HCD marketing, the other two being the development of alternative synthetic formulations of progesterone and the extension of HCD indications to treat acne. These drugs, however, have provided no meaningful added benefits to fertility management. Further, MS marketing is not new; in fact, it is as old as HCD. Advertisements for Enovid in the 1960s had the following slogan: "Enovid® will postpone menstruation…safely…surely" (« Enovid® », 1961). What is new, however, is a "need"-mongering in advertisements that seeks to convince women to supress their menstruation, and not simply to control their reproductive functions (Junod et Marks, 2002).

Medley-Rath and Rimonds (2010) offer an explanation for this rather peculiar aspect of HCD promotion: as there are now dozens of products on the market, manufacturers must convince both women and healthcare providers that their product is best suited for the expectations and needs of each woman. Unlike most drugs, HCDs invite shared decision-making motivated by a desire for convenience rather than the treatment of a medical problem, and this often begins with a woman's interest in a particular product, followed by a conversation with her physician and then a shared decision about which product is most appropriate (Till, 2015). As with other lifestyle products, the entry point for drug promotion is primarily the consumer. This represents an ideal situation for advertising, because exposure to DTC communications (DTCC) – which encompasses advertising (DTCA) and information (DTCI) – effects women's expectations and their requests for specific drugs (Bélisle-Pipon et Williams-Jones, 2015a), and physicians' prescribing behaviour (Mintzes et al., 2003). To make their product stand out from the

competition, manufacturers must therefore play-up the necessity for women to take a product (theirs) that is tailored to a woman's particular needs and which will foster a more fulfilling life.

While most HCDs are marketed as "convenient", "easy to use" and "worry-free" (Medley-Rath et Simonds, 2010; Watkins, 2012), the use of positivist language (one that only emphasizes how the drug will fulfill and enhance their daily life[22]) involves a rhetoric of empowerment that highlights the transformational aspect of MS drugs (no bleeding, no risk of pregnancy), in comparison with regular HCDs (monthly bleeding, no risk of pregnancy). This change in discourse regarding the benefits of eHCDr—from a medical intervention to treat the discomforts associated with clinically-proven menstruation problems, to an issue of convenience—stems both from women's willingness to adopt eHCDr that significantly reduces or eliminates menstruation (Glasier et al., 2003; Shakespeare, Neve et Hodder, 2000; Sulak, Kuehl, Ortiz et Shull, 2002), and a recognised added-value of this new market for manufacturers (Mamo et Fosket, 2009).

The Rise of Menstruation Suppression Advertisements

The past two decades have witnessed the emergence of a new discourse about menstruation, particularly in North America. In the past, periods were considered a natural part of being a woman. During the 1970s and 1980s, surveys showed that most women considered that it was unacceptable for women not to have periods (Glasier et al., 2003) as they were a collective experience and an important part of a woman's identity (Young, 1997). Starting in the early 2000s, monthly menstruation began to be seen by some physicians and relayed by the media as unnecessary and even potentially unhealthy (Johnston-Robledo et al., 2006). Although it was already possible for a woman to suppress her monthly bleeding by skipping the placebo pills of her traditional oral contraceptive (Sulak et al., 2002), this off-label use was often for special occasions and for short periods of time, such as vacations, honeymoon, or during religious holidays (Andrist et al., 2004; Glasier et al., 2003). Prior to 2003, no drug on the market was approved for this specific indication (Watkins, 2012). The change in perception regarding

[22] Good examples are slogans such as: "fulfillment being ahead", "new choice for her future", "Don't wait another month to discover your possibilities" and "worry-free".

periods occurred shortly before the commercialization of drugs specifically designed to reduce the frequency of or simply eliminate menstruations. Just prior to the marketing of these products,[23] Johnston-Robledo and colleagues (2006) showed that in the popular press, MS was already cast in a rather positive light. They found that proponents of MS were twice as likely to be cited in popular media and that "monthly menstruation was frequently described not only as messy, inconvenient, bothersome, but also unnecessary, and even unhealthy." At best, periods were presented as an unnecessary annoyance, and at worst, as a health risk (Hitchcock et Prior, 2004).

This reversal in popular discourse is consistent with Roberts' (2004) findings that marketing for a host of feminine products (for instance, tampon advertising that aim to sanitize, deodorize and hide menstruations) increasingly disconnects women from their corporeality. "Although no longer confined to menstrual huts in Western culture, women must nevertheless hide their menstrual cycles, and the marketing of products that allow them to do so emphasizes an ideal of super-femininity, modesty, and decorum, promising women a sanitized, deodorized, and fresh bodily presentation." (Roberts, 2004, p. 22) This disconnect is very much present in HCD promotion, where "DTC advertisements present menstruation as an undesirable condition for women that is unnecessary, unnatural, and detrimental to one's true identity" (Woods, 2013, p. 270). For instance, in campaigns promoting the drug Seasonique, menstrual periods are presented as "punctuations" or "interruptions" in women's daily lives that the drug promises to correct (Woods, 2013, p. 268). Not surprisingly, the very availability of HCD has influenced the understanding and experiences of women in relation to their menstruations, and affected their perception of menstrual suppression. As noted by Granzow (2007, p. 621): "ideas about femininity, health and embodiment have shifted in relation to changes in particular menstrual-suppressing biotechnologies".

Initially prescribed for clinical indications (such as dysmenorrhea and endometriosis), an extended HCD regimen soon became an option for women without these conditions. Choice and convenience quickly replaced medical necessity in manufacturers' promotional campaigns. A

[23] Seasonale was already undergoing clinical trials for market approval.

study by Woods (2013) shows the full extent of the rhetoric of choice in DTC campaigns. The manufacturers of major contraceptive drugs such as Loestrin, Seasonale/Seasonique and Yaz have focused on choice and the concept of women's control over their own bodies. Presenting HCDs as means of empowerment, these ads recount menstrual experiences as a constant fight by women to reconnect with their true identities. HCDs are even presented as an emancipatory technology, exemplified by the overarching question "Do you feel like half of the month isn't yours?", which is the foundation of the so-called educational website[24] "Understand PMDD" (Premenstrual Dysphoric Disorder), sponsored by Bayer.[25]

With the influence of drug promotion, a change appeared in the popular and medical ethos about MS that contributed to identifying all women as being at-risk for menstrual health problems (and thus legitimate subjects for treatment):

> Instead of arguing that menstrual suppression is best for women with serious, well conceptualized menstrual health problems such as dysmenorrhea or endometriosis, professionals recommended menstrual suppression for women with 'PMS', any 'menstrual health problems' and women already using oral contraceptives. Arguably, any menstruating woman could place herself in one of these categories (Johnston-Robledo et al., 2006, p. 358)

In deploying a feminist argument of emancipation to support this broader use of HCD, manufacturers have participated subtly in the very reshaping of women's identity construction (Mamo et Fosket, 2009). This social influence was made possible by tying drug promotion to a popular ethos (promoted in mass media and by professional associations) (Association of Reproductive Health Professionals, 2008; Johnston-Robledo et al., 2006) already skeptical of the importance of menstruation. The promotion of eHCDr thus played on the conviction that it was not only possible but even advisable for women to use a biomedical intervention to more fully express their corporality and their autonomy, in order to live a life without the inconvenience of menstruation. Discourse in favour of MS generally starts with the assumption that women are already taking an HCD, thus it is an easy and logical next step to switch to

[24] In its marketing strategy for Yaz, even before the launch of the product, Bayer "created an unbranded education campaign to drive engagement with young women" (Chester, Mierzwinski, Simpson et Dixon, 2010, p. 105).

[25] The degree of intensity of promotional activities is useful for understanding, in part, the motivation of the company: in 2010 Yaz was the best-selling contraceptive in the US, and 58% of all Bayer's pharmaceutical advertisement expenditures in the same year were spent on the drug's promotion (Applequist, 2015).

eHCDr (Hitchcock, 2008). This step is taken because, it is argued, most women desire a decreased frequency of their menstrual bleeding (Benson et Micks, 2015). and so legitimately seek a situation seen as desirable, i.e., less menstruation. Yet, a Cochrane study found no significant improvement in satisfaction by women taking eHCDr (Edelman, Micks, Gallo, Jensen et Grimes, 2014). Regardless, MS is cast as a personal choice by autonomous women, one they can make without any negative consequences for their own health or reproductive capacity, and one that will ultimately improve their lives.

While MS can indeed be autonomously chosen by women, a feminist critique could point to the historic fact that society has been androcentric or male-centred for centuries. As Margaret Little explains:

> Under androcentrism, man is treated as the tacit standard for human: he is the…unstated point of reference for what is paradigmatic of or normal for humans. …treating man as the human norm affects, in subtle but deep ways, our concept of 'woman'. …Because man has been fixed as the reference point for so long, part of our very conception of woman has become the conception of 'other'. …[I]n the end, it is a short step to regarding aspects of woman's distinct nature as vaguely *deviant*. (Little, 1996, p. 3)

The social perception of the male body as the norm casts menstruation as a 'deviation' from the 'normal' function of the human body. As such, MS can be presented, through ads, as finally 'normalizing' the female body, promoting equality and leveling the playing field, not only in social and economic terms, but also at a biological level. A fundamental aspect of female biology is thus conceptualized as a "disorder" that needs to be corrected through medical intervention. MS can thus be seen as an alarming step in the direction of viewing women's bodies through an androcentric lens.

An example of this androcentric perception can be found in a news story that accompanied the FDA approval of Lybrel in 2007 (Donalson James, 2007). Entitled "Gender Bender: Redefining the Curse of Menstruation", the article talks about menstruation as what "historically set women apart from men". It quotes the humorous yet telling popular saying "never trust anything that bleeds for seven days and doesn't die", which captures perfectly the notion of menstruation as

deviation from the expected human "male" norm, and thus MS as an effective means of "normalizing" women.

Risks associated with HCD

HCD promotion, and its presentation in the popular media, focuses mainly on choice and control over a woman's body, and the risks are generally downplayed. There is little information about delays in the return of fertility following HCD cessation (Abrams, 2008; Johnston-Robledo et al., 2006). In the case of the common use of HCDs (i.e., not specifically to achieve MS), some physicians claim these drugs have no effect on fertility return, something that is also implicit in most advertisements (Weir et Black, 2007). However, since the introduction of HCD in the 1960s, many studies have found a short-term delay before a woman is able to conceive (Bracken, Hellenbrand et Tr, 1990; Chasan-Taber et al., 1997; Hassan et Killick, 2004). Yet, as noted by Farrow and colleagues, the "use of oral contraceptives and subsequent fertility has not been extensively studied" (Farrow et al., 2002, p. 2756). It is generally acknowledged that the median time to conception after discontinuation of oral contraceptives (regardless of drug formulation) is about three to six months (Bagwell, Thompson, Addy, Coker et Baker, 1995; Jain et Ressler, 2010; Linn, Schoenbaum, Monson, Rosner et Ryan, 1982). Other forms of eHCDr (primarily products staying in women's bodies for an extended period of time) may lead to significantly longer delays in return to fertility (as calculated until an actual conception occurred): the median time when using intrauterine hormonal devices (e.g., Mirena IUD) is about four months, and increases to ten to twelve months for injectable products (e.g., Depo Provera) (Jain et Ressler, 2010). Further, other factors can have a significant impact on the return of fertility, such as age (over 35), obesity, and menstrual disturbances (Hassan et Killick, 2004), causing certain women longer delays in regaining fertility after ceasing to use HCD.

There is consensus that eHCDr do not have permanent or irreversible effects on female fertility (Hitchcock, 2008; Jain et Ressler, 2010). However, no longitudinal studies have been conducted specifically to examine the effects of use over periods of time greater than five years. This is particularly surprising given that HCD (and eHCDr) are mostly used by young women for delaying their first pregnancy, and they are increasingly being promoted for use by adolescents and young women who are sexually active, until they want to conceive (McPherson, 1999;

Wilkins, Johansen, Beaudet et Neutel, 2000). Many women will therefore be using HCD continuously (or using eHCDr with brief interruptions for planned pregnancies) for 2 to 3 decades. This is not surprising considering that in the US, 53% of girls aged 15 to 19 using contraception are taking HCDs (Jones, Mosher et Daniels, 2012). Although some studies indicate that there may be a protective effect of prolonged used of HCD, such as preventing the damaging progression of endometriosis (Vercellini, Ragni, Trespidi, Oldani et Crosignani, 1993; Vessey, Villard-Mackintosh et Painter, 1993), Hitchcock and Prior (2004) identified additional safety concerns that have not been addressed in the medical literature, such as bone and breast health, resumption of typical ovulatory cycles and fertility, and the impact of eHCDr on the development and health of adolescents (possibly because hormonal contraception suppresses a developing system). HCD may also have effects on mental health, with some studies noting a marked increase in the risk of depression (Skovlund, Mørch, Kessing et Lidegaard, 2016). Additional studies are clearly needed to investigate eHCDr's protective and deleterious effects, and in a context of use by women over decades, given that "many possible risks (e.g., osteoporotic fracture, breast cancer) take decades to emerge and so are difficult to assess." (Hitchcock, 2008, p. 703)

It is disturbing, then, to note that the risks (and scientific uncertainly) associated with eHCDr are often minimized or even ignored in the popular media. In their study of the coverage of MS in North American popular magazines, newspapers, and on-line publications, Johnston-Robledo and colleagues found that "Medical benefits were discussed in 95.5% of the articles, whereas only 72.7% discussed the risks. When risks were mentioned, 69% of the time they were downplayed." (Johnston-Robledo et al., 2006, p. 357) Moreover, only 41% articles mentioned the absence of long-term research on eHCDr and MS safety, and only 11% mentioned that such research was necessary.

Studies analyzing the return of fertility usually refer to "median time", and so for many women these numbers underrepresent their own reality. In these studies, the median time is the moment when 50% of women again became fertile (i.e., their periods had returned and they were able to conceive). Since this is the value usually used to describe HCD's long-term effects, it excludes the experience of half of the women for whom return to fertility took longer. Linn and colleagues

(1982) found that for almost 20% of women, return to fertility took 13 to 15 months. Since these women conceived without medical assistance (e.g., ovarian stimulation, *in vitro* fertilization), they cannot be regarded as infertile. The authors thus argue that 15 months is a more accurate interval for evaluating (in)fertility of former HCD users, so that women do not receive unnecessary assisted reproductive treatments (Linn et al., 1982). However, a common definition of infertility is an incapacity to conceive after 12 months (Zegers-Hochschild et al., 2009). Women could thus be misdiagnosed as being infertile and referred for fertility treatments when in fact their inability to conceive is actually the result of long-term use of HCD, and they would most likely become fertile again, without medical intervention, given sufficient time (e.g., more than 15 months).

That relevant, reliable and balanced information about MS, including specific data about eHCDr, is not adequately communicated to women by drug manufacturers is particularly worrisome. According to the Society for Menstrual Cycle Research, it is especially important that women be cautious when choosing MS and that they are informed of potential risks, because menstruation is not a disease (Society for Menstrual Cycle Research, 2007). It is crucial that women know that eHCDr is not only a means of inducing MS, but that they "also suppress the complex hormonal interplay of the menstrual cycle" (Society for Menstrual Cycle Research, 2007, p. 29). This suppression may therefore hide—and also interact with—underlying reproductive health problems in a manner that may go unnoticed during the years that women are on eHCDr and for which there is little knowledge.[26] These problems will be revealed only at the cessation of use, possibly when desired conception does not occur. Women are thus unable to prepare ahead of time for this new reality (i.e., delayed fertility or potential health problems), in anticipation of a future pregnancy. In such a case, the woman will be referred to assisted reproductive medicine after diagnosis of infertility, possibly without ever having known she had reproductive issues. This scenario does not promote informed choice. There are thus at least two particularly vulnerable populations: the 20% of women who may take up to 15 months to

[26] For instance, women with polycystic ovary syndrome (PCOS)—which affects 1 in 10 women of childbearing age and often renders them infertile—have a higher risk of developing glucose intolerance, which is partially related to their insulin resistance. For the treatment of their syndrome, these women are often prescribed HCD. Ironically, recent studies have shown that these drugs may actually lower insulin sensitivity and glucose tolerance, thereby putting these women at risk for type-2 diabetes. HCD may thus be contributing to insulin resistance in PCOS-afflicted women, which is already an important factor of their syndrome, alongside infertility. See Diamanti-Kandarakis et al. (2003).

conceive without medical assistance, and hence might be mistakenly diagnosed and treated as infertile; and those with undiagnosed reproductive health problems. Both would benefit greatly from being better informed about the effects on their fertility of eHCDr and MS in general.

Implications for autonomy

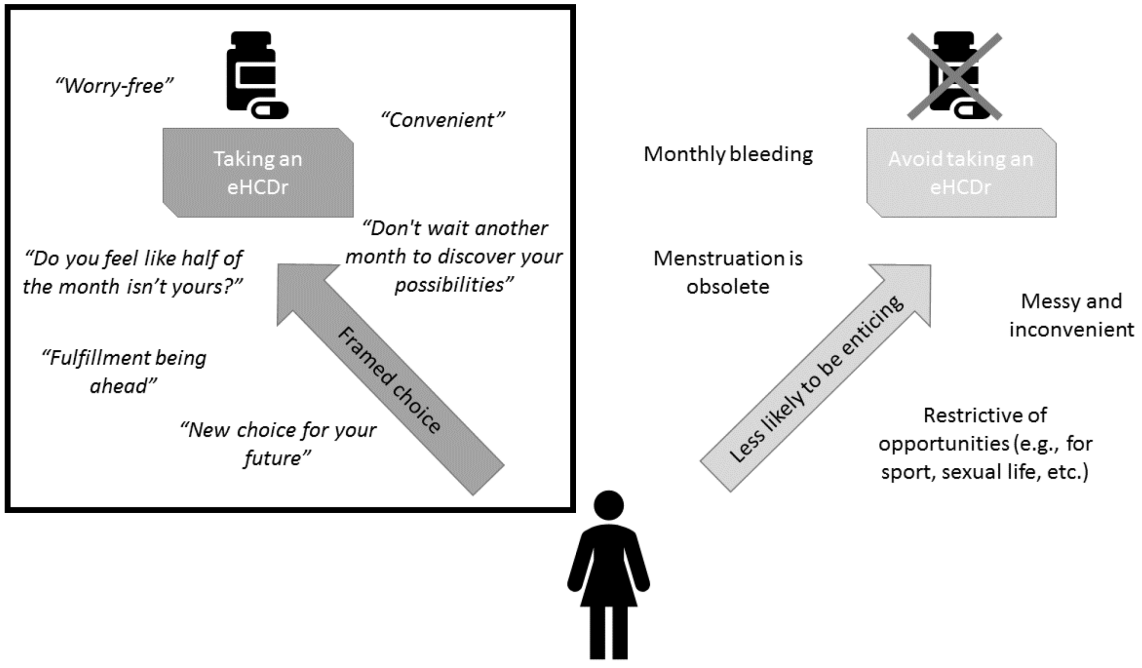
Choices related to lifestyle and convenience often conflict with considerations related to long-term health and fertility, and the former may severely affect the expression and the fulfillment of the latter (and vice-versa). For instance, certain lifestyle choices can limit the biological possibility of having children (e.g., training to become a professional athlete can provoke time-limited amenorrhea), but if this consequence is foreseeable and deemed acceptable by the woman concerned, and the decision-making has been informed and as much as possible free from undue influence (e.g., encouragement, but not pressure from parents and coaches of young female athletes), it does not raise particular ethical challenges for a woman's autonomy, including her reproductive autonomy. Broadly speaking, reproductive autonomy refers to the freedom to choose whether and when or not to have children. As Laura Purdy argues, "[n]othing would advance women's welfare more than respecting their reproductive autonomy" (Purdy, 2006, p. 287). In that sense, it is worth examining how drug promotion advances or impedes women's welfare and choices.

Framing choices

The issue at hand is not which choice women end up making regarding the use of HCD, but rather why they are not provided with accurate, unbiased and complete information necessary to make such choices. As discussed previously, eHCDr marketing promotes idealized views of these products, DTCC rhetoric casts menstruation in a rather negative light, women's emancipation is constructed by the use of eHCDr, and risks are trivialized. This way of presenting menstruation and associated medications can shape consumer choices and alter the decision-making process. The construction of choices by promotional messages has both theoretical and empirical support and is often used in the world of advertising through the *framing effect*. This effect implies "that a consumer's decision in choice involving risk can be influenced not only by the objective features of alternatives, but upon whether the information about that risk is phrased, or framed, as a gain or a loss." (Ho, Mursch, Ong et Peittula, 1998, p.

108) Framing will often involve a general lack of comprehensiveness and the omission of certain crucial information; and even "ethical choices may be influenced by frames" (Kellaris, Boyle et Dahlstrom, 1994, p. 69). The aim is to influence the choice by orienting the presentation of a certain reality by incompletely or partially presenting data relevant to informed decisions. Health-related messages that work best are those negatively framed with a "focus on the adverse consequences or benefits lost from not using a product" (Homer et Yoon, 1992, p. 19). In the case of eHCDr, menstruation is depicted as negative and even unhealthy. Adverse consequences pertain to a woman's loss of control over her body[27], diminished productivity, and an overall lack of fulfilment. The result is that considerations of lifestyle and convenience receive much more attention and positive light than those related to risks and reproductive contingencies, or to menstruation's social context and the social role of women.

Framed choices. When DTCC embraces a rhetoric of choice, by only highlighting women's lifestyle consideration and downplaying risks, this has the effect of narrowing choices (see Figure 10).



[27] With slogans such as "Do you feel like half of the month isn't yours?".

Figure 10. Framed choices following drug promotion rhetoric

An example of framed choices can be found in the self-diagnosis tools provided on Yaz's website for US patients that, according to Ebeling (2011, p. 830), were mainly "serv[ing] as a pathologizing checklist for women's emotional and bodily experience of menstruation" and as a "standardization instrument to categorize what is biologically normal and what is not." Moreover, according to Ebeling (2011, p. 830): "the YAZ diary functions as a technology of self-regulation that disciplines the patient's bodily experiences into a marketing diagnostic framework [and] whilst portrayed as being a tool for patient empowerment, is also an indexing instrument for pharmaceutical marketing to determine the field of diagnostic possibilities." A woman's choice is thus constructed around options to take control over some of her bodily functions in order to live a life more in line with what she wants (or what marketers imply she wants), by eliminating the discomfort associated with functions seen as non-essential or even pathological and repulsive, that is, menstruation (Ebeling, 2011).

Advertisements thus play on two sides to frame the reality surrounding their product: positively presenting the benefits and inflating who is medically at-risk of menstrual health problems and thus would greatly benefit from the drug. A value-laden vocabulary is used to present the ads—with slogans such as "fulfillment being ahead", "new choice for her future", "Don't wait another month to discover your possibilities" and "worry-free"[28]—with the underlying message that it is possible to suspend fertility to have a more satisfying life and still have the freedom to resume fertility when relevant in a woman's life, and without risk or need for concern.

With the influence of drug promotion, the change in the popular and medical ethos about MS has also contributed to framing choices by identifying all women as being at-risk and necessitating a MS treatment. From this broadening of categories of HCD use follows inevitably a further medicalization of healthy women. It is thus important—and in line with recommendations of the Society for Menstrual Cycle Research (Society for Menstrual Cycle Research, 2007)—to better inform women about the risks of eHCDr, especially since it has been

[28] Excerpts from advertisements for Yaz, Seasonique and Lybrel.

shown that advertisements for certain MS medications were blatantly minimizing their risks (e.g., Yaz's manufacturer received a warning letter in this regard) (Abrams, 2008). This is all the more important when advertising minimizes considerations that are highly relevant to consumers. For instance, although in the case of lifestyle drugs, the cost of a medication represents the overarching concern for consumers (since they are usually paid for out of pocket, and less frequently reimbursed by public and private insurance) (Stolk, Brouwer et Busschbach, 2002), when asked to value the most important concerns with regards to eHCDr, both women and physicians noted that "long-term health effects, side effects and fertility were more important than the cost" (Andrist et al., 2004). This should raise a red flag since advertising is not answering consumers' needs for information (Bélisle-Pipon et Williams-Jones, 2015b).

Framed choices pose serious consequences for autonomy, since the recipient of a promotional message will more likely be convinced that her emancipation involves taking an eHCDr, notwithstanding the risks, or the lack of knowledge about a long-term use. Much more is at stake with pharmaceutical marketing in comparison with mass consumer products, like clothing and electronics. Contrary to most other consumer goods, drugs are ingested, injected or inserted by women; their very invasive nature may foster the impression that they work, since they directly interact with their body. Also, the potency of pharmaceutical drugs necessarily increases requirements for unbiased information and for effectively fostering empowerment. The problem is not the choice made (e.g., favouring convenience rather than avoiding the consequences for fertility), but the environment of choices in which the consumer is placed, which shapes her reality through a narrowed frame. This distortion of reality instrumentalizes women's own legitimate desires for fulfilment in various aspects of their lives, constructing a particular view of desirability – through social and medical contingencies fueled by promotion – that they might otherwise not choose. Hence the interest of distinguishing between various understandings of how autonomous choices are situationally expressed in the balancing between lifestyle and reproductive choices, and their intrinsic moral expectations of self-determination.

Open choices. By comparison, an open view towards the multiple facets of human life requires consideration of whether and how values and preferences can enter into conflict. The goal is to establish whether individuals who must make a therapeutic (or convenience) decision have the

opportunity to consider alternatives that are realistic, reasonable and salient to their own context. For choices to be open, they need to be perceived as real choices that are genuinely available, and so presented in a way that enables individuals to weigh competing implications (see Figure 11). Open choices can thus foster autonomous decisions, ones that are "based on relevant knowledge, consistent with the decision-maker's values and behaviourally implemented" (Marteau, Dormandy et Michie, 2001). Facts must therefore be accessible, unbiased and their presentation should not favor an outcome (intentionally or not) unfavorable to the individual, nor make use of peculiar contexts to favor certain choices. So even if there is access to sufficient, comprehensive and reliable information, a social context – such as one that frames women as needing to eliminate menstruation in order to comply with social standards – may nonetheless narrow their possible (and legitimate) choices (O'Connor et O'Brien-Pallas, 1989), which must be excluded in a posture favoring open choices.

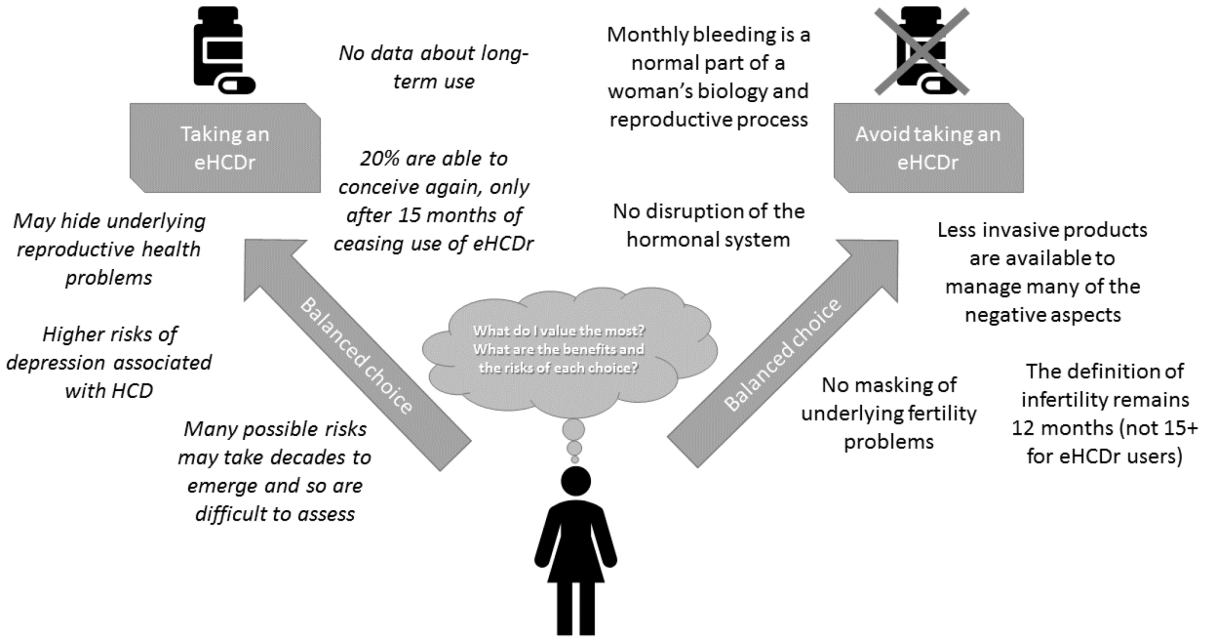


Figure 11. Open choices with access to relevant and reliable data

An open choice analysis of how information is conveyed takes into consideration social influences and mechanisms of persuasion and control that surround decision-making. Further, it highlights the fact that all choices have consequences; adopting a desired lifestyle may affect

other aspects of one's life. The possible long-term impact of eHCDr on fertility is an important consideration that should inform choices about its use. Marketing that lacks accurate and reliable information thus weakens autonomous choices and undermines women's reproductive autonomy. Moral judgments about the influence of rhetoric on consumer choice must therefore consider more than a surface-level understanding of how facts are presented and choices framed. As such, to be ethically justifiable, DTCC must foster an open choice perspective that actually supports consumer empowerment and the ability to make informed decisions.

Is drug promotion reframing the conditions in which autonomous decisions are made?

The construction and marketing of an "emancipated life", free of the "constraints imposed by the female body", is a commercial rhetoric that attempts to shift the social perception of menstruation from a natural function to a harmful occurrence that impedes women's self-determination. First, this messaging limits reproductive autonomy by failing to mention the delay between contraceptive cessation and a potential pregnancy, or provide aggregate data from high-quality long-term research (due to its non-existence). Second, it feeds into a social transformation in the perception of menstruation that may end up narrowing women's choices and thus their overall personal autonomy. Such rhetoric is grounded, according to Kissling (2013, p. 490), in an individualistic view of autonomy[29] and of the self-"[imposing] an idealized, docile, non-menstruating feminine body, ready for full-time participation in the neoliberal economy". The marketing of menstrual suppressors and framing of certain autonomous choices is thus favoured by an alignment of interests between women's desire for control over their bodies, social expectations regarding women's productivity, and the economic incentive to sell products. Such an alignment may be "consistent with neoliberal economic policies" (Kissling, 2013, p. 492), but hardly captures all that is pertinent to reproductive autonomy.

Control of their reproduction capability promotes not only women's reproductive autonomy (i.e., the choice whether and when to have children), but also their personal autonomy (i.e., their

[29] Individual choices and efforts determine who we are and what we achieve, but are also contingent upon "collective action or structural impediments". Kissling (2013, p. 491) argues that the current neoliberal framework "re-rationalizes [autonomy] according to neoliberal values that replace classic liberal values of human rights, equality, and liberty with primacy of the contract and the marketplace, and the individual." Therefore, all values and considerations are "on an equal footing of individuality", seen as an overarching priority and determinant.

overall ability to determine the course of their lives). Yet, it may also—paradoxically—narrow their future options. Rothman (1993) demonstrates this through the example of the choice regarding how many children to have. Prior to accessible contraception, natural capacity determined the size of families. But the social acceptability of contraception gradually narrowed women's freedom because it also framed their choice to have a large family as 'irresponsible', and made it both socially and economically almost non-viable in many social contexts. The same phenomenon is evident in the context of prenatal testing. While often described as a boon to women's reproductive autonomy, allowing them control over what children they choose to have, the mere existence of prenatal testing creates social pressure on women to opt for its use. Here again, the technology tends to narrow the possibility of rejecting the test, by framing such a choice as socially unacceptable and depicting a woman who makes this choice as an irresponsible mother, even before birth. Women who opt not to test and have an affected child often describe feeling judged by healthcare providers and society at large (Lewis, Hill et Chitty, 2016).

The issue of social framing and social pressure also applies to the use of eHCDr. While it is described by marketing efforts as liberating women from the burden of menstruation, over time – if successful – it may transform the social view of menstruation and make it an 'irresponsible' or even 'repulsive' choice that women should not make. Choosing to 'suffer' from a natural predicament that has an easy, medicalised, and socially acceptable 'solution' may be perceived as a non-viable choice because it slows a woman down, making her seem less attractive, unproductive, and less competitive. In the past, menstruation was a sign that a woman was not pregnant (Martin, 1999) (or, as presented by Coutinho[30] and Segal, periods were a sign that the reproductive system has failed) (Coutinho et Segal, 1999), *ergo* that she was not fulfilling her reproductive duty. In the context of eHCDr, periods are depicted as undermining the productivity expected of modern women (Archer, 2006; Hitchcock, 2008) who should not be preoccupied or slowed down by their fertility, until the time is right.

[30] To better contextualize this assertion, it is pertinent to know that Coutinho is the scientist who led the development of Depo-Provera, the first injectable eHDRr.

Adherence to *external* standards – that are broadly related to the notion of femininity (appearance, body shape, cosmetics, etc.) – lead to "a body [that is] socially constructed through appropriate practice" and women can be socially sanctioned by shaming and limitation of life opportunities if they are not complying with a patriarchally-idealized feminine body (Bartky, 1998). To be feminine, a woman must not only correspond to external body norms (appearance, weight, size, depilation) but also to internal norms, by correcting menstruation, considered by patriarchal powers as a deviation from the male body norm. eHCDr plays an active part in fostering this alignment of women's bodies to "patriarchal standards of bodily acceptability" (Bartky, 1998). Women become, then, self-policing subjects, having internalized social standards into their identity and construction of self. This framed self-regulation must therefore be taken into account as an insidious factor that can limit autonomy, and so affect individual emancipation and autonomous decision-making.

Another case in point is the recent debate surrounding the policies of some companies that include, in their benefits package, egg freezing for female employees (Baldwin, Culley, Hudson et Mitchell, 2014; Mertes, 2015). While in this case fertility preservation is achieved by "putting on hold" this biological material – possibly in order to pursue a career prior to becoming a mother (Mertes, 2015) – MS fertility suspension is achieved by pausing biological functions, allowing women full control not only over their fertility but also over their lives more broadly. In both cases, postponing fertility can have adverse health consequences (egg freezing requires hormonal intervention and an invasive procedure) of which women should be better informed (Martinelli, Busatta, Galvagni et Piciocchi, 2015). And while both are personal choices that ought to be respected, social expectations and pressures must be taken into account when considering the full impact on women who are being medicalized even if they are in perfect health (Martinelli et al., 2015; Ravitsky, 2014; Ravitsky et Lemoine, 2014).

Toward genuinely empowering messages?

Decades of 'emancipation' and 'empowerment' discourse regarding HCDs have forearmed, we argue, manufacturers against critics who may claim that their drugs and promotional messages interfere with women's lives. Further, this rhetoric of empowerment also resonates with the actual social ethos about MS drugs, so the persuasive power of eHCDr marketing strategies

should be a source for concern. The primary interest is not the advertisements' purported interest in women's welfare (physical, psychological, or emotional), but the commercial success of the advertised drug (Bélisle-Pipon et Williams-Jones, 2015a; Mulinari, 2016b). Thus, in addition to not providing relevant information on eHCDr risks, the social and medical environment fosters the medicalization of menstruation and discourages women from making certain choices, notwithstanding what they may consider to be valid and relevant. It is all the more concerning that, for most women, there are no medical reasons to opt for this technology, since eHCDr is inherently promoted and consumed as a lifestyle drug. To comply with the social contract (in the philosophical sense) allowing (and justifying) drug manufacturers to use DTC communications, they should refrain from framing choices and be held more accountable for the messages they convey (Till, 2015).

To truly empower women, it is essential to promote informed choices and to support a comprehensive notion of open choices, and personal and reproductive autonomy. This necessitates ready access to trustworthy informational resources so that women can make decisions about whether or not to suppress their menstruations, and to assess the implications of a potential delay in the return of fertility. To be autonomous, women must have the ability to act and make decisions in line with their values, desires and beliefs; but they must also have knowledge regarding the short and long term consequences of their choices, in order to be able to make informed choices and prioritize what is most important and relevant to their lives (Till, 2015). The current situation, which manufactures describe in their messages as one of liberating women by allowing them to take control over important aspects of their bodies, actually limits autonomy since the potential consequences of choices are not presented, but rather swept under the marketing rug. To be clear, we do not argue that MS is not an acceptable choice, but rather that it should result from a truly informed decision. To be convinced by advertising arguments of choice and control, without any knowledge about fertility delays, possible masking effects, and the lack of long-term research, is a risky venture that may have an unexpected impact on women's reproductive autonomy.

Conclusion

Caution is required regarding the content of promotional messages that foster a purported enhanced-lifestyle while insufficiently informing women about the consequences of the medication required to achieve such a life. Permitting such messaging and allowing manufacturers to "hide" important information can limit the expression of women's (reproductive) autonomy; and it is neither fair nor respectful to women. Regulators must thus be careful when implementing rules to control the content of information and advertising for menstrual suppressors, and be sensitive to the use of rhetoric that narrows choices and is detrimental to women's autonomous decision-making. And the pharmaceutical industry should recognize that it is not in the interests of its customers to be framed into a reality that is not theirs; for this industry to act in this way is to fail in its social responsibility towards the beneficiary of the drugs, women. Assessment of the informational value of direct-to-consumer communications should be based on a comprehensive understanding of what can influence informed decision-making. In order to achieve this, regulators (either in government agencies, third-parties or industry oversight bodies) must recognize and reject the framing of the rhetoric of women's autonomy in drug promotion as simply a matter of convenience and "lifestyle choice", and instead use a more critical understanding—in both health policy and drug regulation—of the social and cultural factors (expectations, pressures, social constructs) that frame "womanhood" and seek to advance a rather limited view of women's available choices and of what is necessary to foster autonomy. Specifically, we argue that caution is required on the part of regulators when approving promotional messages for lifestyle drugs, such as eHCDr for MS, that do not adequately inform women about the consequences of the medication required to achieve such putatively augmented-lifestyles. Women's autonomy is not well served by permitting the use of a biased rhetoric of choice.

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Prendre en considération les impacts de la rhétorique sur les choix possibles des consommateurs

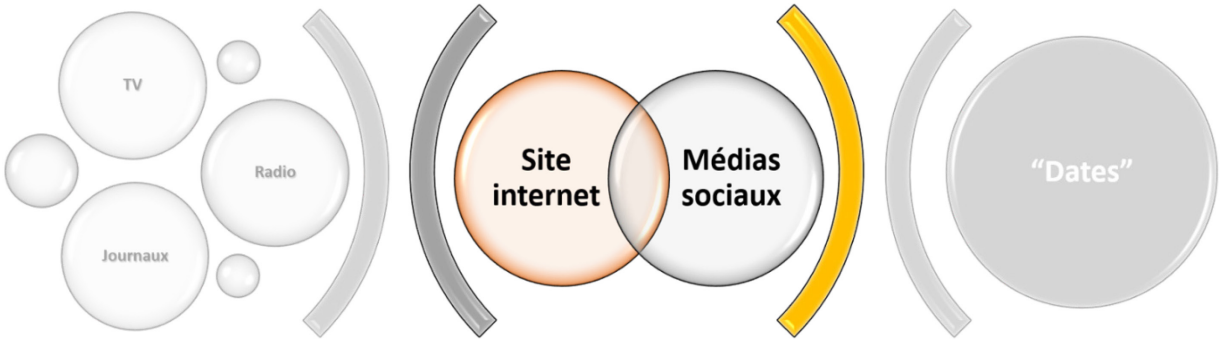
Le cas des suppresseurs de menstruations permet d'illustrer que les notions d'autonomie et de prise de décision des consommateurs peuvent être instrumentalisées dans le cadre des campagnes de promotion dans le cadre des CDCM. Cette mise en scène de l'autonomie des consommateurs a pour but de renforcer l'idée que certains choix (c'est-à-dire, les solutions pharmaceutiques) sont avantageux, voire nécessaires. Cette emphase sur l'importance de la solution pharmaceutique trouve résonnance tant dans un contexte socioculturel propice à renforcer le message (notamment, un argumentaire fort des contraceptifs pour l'émancipation des femmes et une couverture favorable des nouveaux produits dans les médias) que dans un ensemble complexe de dispositifs (communications télévisées ou radiodiffusées, sites web, outils d'autodiagnostic) mis en place. Le secteur peut ainsi relayer l'information de telle sorte à rendre son message omniprésent et son argumentaire incontournable. Des pratiques qui ont pour effet de limiter les choix possibles de certains consommateurs en quête d'un traitement tout en convaincant indûment les consommateurs en santé qu'ils souffrent d'une certaine condition (notamment en pathologisant certaines fonctions du corps) pour laquelle un traitement leur est nécessaire.

Ce qui se dégage est l'importance de faire preuve de prudence quant au contenu des messages promotionnels louant les mérites (ou mettant en scène la représentation) d'un style de vie amélioré, sans traiter des conséquences potentielles du médicament vendu comme solution. En permettant une telle rhétorique et en omettant de porter une attention particulière au contexte social et culturel dans lequel s'inscrit la campagne, la régulation peut avoir pour effet de tacitement permettre que les CDCM affectent indûment le processus de choix éclairé des consommateurs. L'objectif de cette étude de cas n'est pas d'entamer une discussion sur les diverses conceptions de l'autonomie, mais se limite plutôt à mettre en lumière l'impact de la rhétorique et de la création de besoins sur les processus décisionnels, dimensions essentielles pour l'expression de l'autonomie.

Le cas en appelle aux deux principaux acteurs pour parvenir à mieux encadrer ce type de pratique : les régulateurs et l'industrie. Les régulateurs doivent s'assurer que les règles mises en

place pour contrôler le contenu des CDCM prennent en compte leur impact sur le façonnement des choix et de la prise de décision éclairée des consommateurs. L'industrie, pour sa part, devrait reconnaître sa part de responsabilité quant au façonnement des choix des consommateurs et qu'il n'est pas dans l'intérêt des consommateurs de présumer qu'un certain médicament leur est destiné et représente la seule solution à un problème de santé existant ou induit par la publicité. Les prochains cas mettront la table au partage des responsabilités entre les régulateurs et l'industrie. Régulateurs comme industrie ont un rôle à jouer pour assurer que les consommateurs reçoivent une information de qualité promotrice de choix éclairés répondant à des besoins authentiques.

Chapitre 4. La communication à travers Internet et les médias sociaux



Dans la dernière décennie, les CDCM électroniques (eCDCM) ont connu une croissance fulgurante par le truchement de sites web faisant la promotion d'un produit ou visant la sensibilisation des patients à une condition particulière. Ces sites servent souvent de complément à une campagne dans un média traditionnel afin de fournir plus d'informations aux consommateurs que peut en contenir un message télévisé ou radiodiffusé de 30 secondes ou d'une minute. En plus de véhiculer son message, l'utilisation et la promotion d'un site web, où les consommateurs peuvent trouver plus d'informations et des tests autodiagnostics, est, pour un fabricant, une excellente façon de continuer la conversation et d'assurer leur engagement par rapport aux produits ou aux conditions médicales annoncées.

Plus récemment, l'industrie pharmaceutique s'est lancée dans le web 2.0 et les médias sociaux (Facebook, Twitter, Instagram, Google+, etc.). Au début, l'industrie a été plutôt réticente à s'aventurer dans un univers aussi interactif où une bonne partie du contenu est généré par les réactions des utilisateurs (Katsanis, 2016). La crainte principale était la possibilité de perte de contrôle du message, de l'image d'un produit ou d'une campagne. Une autre inquiétude était que les consommateurs rapportent massivement des effets secondaires, que les fabricants sont tenus à signaler aux agences règlementaires, qui pourraient nuire à l'image des produits. Les avantages – comme le faible coût, la facilité de déploiement et la possibilité d'interagir avec des auditoires spécifiques et potentiellement réceptifs quant au produit – l'ont cependant emporté sur les craintes.

Tandis que les agences règlementaires ont lancé des politiques prenant en compte les spécificités (comparativement aux médias traditionnels) des premières formes d'eCDCM, les médias sociaux n'ont pas encore n'ont pas fait l'objet d'un effort régulatoire substantiel (Food and Drug Administration, 2016). Ces formes plus récentes d'eCDCM sont généralement régulées de façon ad hoc par l'adaptation des politiques prévalant avant l'apparition des médias sociaux. À titre d'exemple, les politiques canadiennes sur la DTCI portant principalement sur les brochures, les sites web et les numéros 1 800 servent de base pour la conformité des communications sur les médias sociaux (Advertising Standards Canada, 2011) bien que les enjeux d'interactivité et d'échange sont substantiellement distincts. Pour sa part, la FDA (2016) a reconnu ce besoin de spécificité et mène présentement des consultations pour établir une règlementation qui s'assurerait que les principes généraux qui guident l'encadrement des CDCM (tel que le *fair balance*) puissent prendre en compte et s'appliquer aux particularités des médias sociaux.

Les enjeux autour des communications électroniques sont traités, dans le présent chapitre, dans deux articles portant sur la campagne canadienne *40desplusde40* sur la dysfonction érectile. Chacun, selon des angles distincts, permet de mettre en lumière les limites des modes de régulation actuels. Quant à l'incidence des médias sociaux, elle est abordée en mettant en perspective l'utilisation d'annonces promotionnelles géolocalisées et ciblées en fonction des particularités des consommateurs.

40desplusde40

Les articles « *Drug Familiarization and Therapeutic Misconception via Direct-To-Consumer Information* » (Bélisle-Pipon, J.-C. & Williams-Jones, B. publié dans le *Journal of Bioethical Inquiry*) et « *Regulating Direct-to-Consumer Drug Information: A Case Study of Eli Lilly's Canadian 40over40 Erectile Dysfunction Campaign* » (Bélisle-Pipon, J.-C. & Williams-Jones, B. publié dans *Healthcare Policy*) s'intéressent à la campagne *40desplusde40* sur la dysfonction érectile (DE) de la compagnie Eli Lilly. Apparue à l'automne 2012, cette campagne est rapidement devenue l'une des campagnes de CDCM les plus importantes au Canada. La campagne tablait sur deux éléments principaux une annonce télévisée de recherche d'aide présentant sommairement la condition médicale et le fardeau de vivre avec une DE qui référait à un site Web appelé *40over40.ca*. Ce site était l'élément le plus important de la campagne, car

il présentait, avec beaucoup plus de détails que l'annonce télévisée, l'état de santé et ses causes possibles, les symptômes et les traitements disponibles, et encourageait les consommateurs à parler à leur médecin.

Conçue dans le respect de la régulation canadienne, plus précisément la politique de Santé Canada concernant la distinction entre la publicité et d'autres activités d'information et les directives des Normes canadiennes de la publicité (NCP), le plus intéressant de cette campagne est qu'elle utilisait des dimensions non régulées afin de *familiariser* les consommateurs aux diverses options de traitement et à les convaincre qu'ils souffraient de DE. Par exemple, elle incluait un outil d'autodiagnostic qui, à l'instar de celui de Yaz vu précédemment, peut être considéré comme pathologisant, au sens où il met à risque des individus qui ne devraient pas être considérés comme nécessitant une solution pharmaceutique. Quoique ces deux articles portent *stricto sensu* sur le contexte canadien en matière de limites et d'ambiguïtés de la régulation, les conclusions des deux articles, à propos de recommandations pour un meilleur encadrement de la DTCI, s'appliquent à tous les pays permettant les campagnes de sensibilisation à des conditions médicales et d'information commanditées par l'industrie, c'est-à-dire une majorité des pays de l'OCDE.

Ces deux articles ont également mené à l'écriture du commentaire *Preparing for the arrival of "pink Viagra": strengthening Canadian direct-to-consumer information regulations* publié en 2016 dans *Canadian Medical Association Journal* (Bélisle-Pipon et Williams-Jones, 2016). Le commentaire est reproduit dans son intégralité à l'Annexe 1. Ce commentaire s'inscrivait dans la foulée de l'homologation aux États-Unis du *flibanserin* pour le traitement du trouble de désir sexuel hypoactif. Sur la base des résultats des deux articles, des recommandations aux décideurs ont été formulées directement à l'attention de Santé Canada pour les conscientiser à des dimensions importantes provenant de campagnes de sensibilisation ayant eu lieu aux États-Unis à propos du *flibanserin*.

Drug Familiarization and Therapeutic Misconception via Direct-To-Consumer Information
J'ai écrit le premier brouillon de l'article. Bryn Williams-Jones a ensuite commenté l'article en ajoutant des informations et des idées pour renforcer l'argumentation et la logique du texte.

Nous avons tous deux révisé de façon critique toutes les versions ultérieures jusqu'à ce qu'il y ait entente sur la version à soumettre à la revue *Journal of Bioethical Inquiry*. Les résultats de l'article ont maintes fois été présentés dans le cadre de congrès scientifiques de de l'UNESCO Chair in Bioethics, de l'International Association of Bioethics (IAB), de la Société canadienne de bioéthique, de l'Association francophone pour le savoir et des Programmes de bioéthique.

Regulating Direct-to-Consumer Drug Information: A Case Study of Eli Lilly's Canadian 40over40 Erectile Dysfunction Campaign

J'ai écrit le premier brouillon de l'article. Bryn Williams-Jones a ensuite commenté l'article en ajoutant des informations et des idées pour renforcer l'argumentation et la logique du texte. Nous avons tous deux révisé de façon critique toutes les versions ultérieures jusqu'à ce qu'il y ait entente sur la version à soumettre à la revue *Healthcare Policy*. Les résultats de l'article ont maintes fois été présentés dans le cadre de congrès scientifiques de l'UNESCO Chair in Bioethics, de la Société canadienne de bioéthique, l'Association francophone pour le savoir et des Programmes de bioéthique.

Médias sociaux

L'article « Using Social Media to Sell Prescription Drugs » (Bélisle-Pipon, J.-C. & Birko, S. (2017) publié dans *Impact Ethics*) s'intéresse aux CDCM diffusées à l'aide de médias sociaux sous forme d'annonces publicitaires (DTCA) ainsi qu'aux pratiques que permet l'état actuel de la règlementation au Canada. L'article ajoute un acteur dans l'équation, c'est-à-dire les pharmacies. Elles sont sujettes aux mêmes lois et pourraient décider de profiter de dispositions qui ne sont pas utilisées par les compagnies pharmaceutiques, soit de faire la promotion du nom et du prix d'un médicament. Elles pourraient ainsi envoyer à des consommateurs ciblés pour leur historique de furetage sur des médias sociaux, donc plus susceptibles de faire des démarches pour se procurer une prescription et ainsi, acheter leurs médicaments à la pharmacie annoncée.

L'idée de cet article a émergé d'une discussion alors que j'animais un club de lecture au sein des Programmes de bioéthique en 2016. Stanislav Birko, en tant que participant au club de lecture, a lancé l'idée dystopique qu'un jour les pharmacies arriveront à envoyer des messages textes aux consommateurs pour leur offrir des rabais sur certains produits. Nous avons poursuivi

les échanges et j'ai rédigé un premier brouillon pour un court article à soumettre à *Impact Ethics*. Nous nous sommes échangés à quelques reprises le texte, le bonifiant un peu plus chaque fois. L'autorat s'est décidé de façon organique et a été approuvé par les deux auteurs.

Drug Familiarization and Therapeutic Misconception via Direct-to-Consumer Information

Bélisle-Pipon, J.-C. & Williams-Jones, B. (2015a). Drug Familiarization and Therapeutic Misconception via Direct-To-Consumer Information. *Journal of Bioethical Inquiry*, 12(2), 259–267. doi:10.1007/s11673-015-9634-8

Abstract

Promotion of prescription drugs may appear to be severely limited in some jurisdictions due to restrictions on direct-to-consumer advertising (DTCA). However, in most jurisdictions, strategies exist to raise consumer awareness about prescription drugs, notably through the deployment of direct-to-consumer information (DTCI) campaigns that encourage patients to seek help for particular medical conditions. In Canada, DTCI is presented by industry and regulated by Health Canada as being purely informational activities, but their design and integration in broader promotional campaigns raise very similar ethical concerns as those associated with DTCA. Specifically, DTCI can be an effective means of familiarizing the public with the scope and benefits of a particular prescription drug and so, like DTCA, can promote increased patient-consumer demand and thus a problematic rise in the prescribing and use of medications that may be neither the most appropriate nor the most cost-effective. Yet, with DTCI the industry is playing within the existing rules and regulations set by health regulators. To respond appropriately to this regulatory incoherence, we argue that DTCI should be regulated as a type of direct-to-consumer *indirect* advertising. Even if the case and specific regulations presented here are Canadian, the implications extend to every country that has a partial or total prohibition on DTCA.

Keywords

direct-to-consumer; advertising; information; prescription drugs; pharmaceutical industry; public policy; marketing campaign; therapeutic misconception; drug familiarization

Introduction

The promotion of prescription drugs is a vast and complex enterprise. Pharmaceutical industry marketing departments use multilayered campaigns to reach as many patients as possible and

obtain maximum exposure for their flagship products (Flowers et Melmon, 1999). In Canada, drug promotion or advertising is relatively limited in comparison with the United States, because the direct-to-consumer advertising (DTCA) of prescription drugs is restricted; an advertisement cannot "make any representation other than with respect to the brand name, proper name, common name, price and quantity of the drug" (Government of Canada, 2016, p. 871-872). This may in part explain why, as one Canadian study has shown, only a few blockbuster drugs are heavily promoted in the media, with the eight most-promoted drugs accounting for 59 percent of drug promotion (Mintzes, 2006). Given these restrictions, from the industry's perspective it may be simply more cost-effective to focus on advertising only those drugs that are already well known to the public, as Canadian regulations prohibit presenting the drug's therapeutic indications. Relying on blockbusters is likely to garner maximum consumer exposure within current regulations and thus to generate the most return on investment. However, there may be other ways for the pharmaceutical industry to build consumer awareness of its products, whether or not these are blockbusters, beyond what has traditionally been described as drug promotion or advertising.

In this paper, we use Eli Lilly's Canadian DTCI campaign "40over40" (for erectile dysfunction) as an example to show that, even if *presented* by industry and *regulated* by Health Canada as being purely informational, such campaigns are nonetheless a form of direct-to-consumer *indirect* advertising (DTCIA). These campaigns can be effective means of building familiarization with a disease and a specific drug treatment and so raise very similar ethical concerns as those associated with DTCA. They should thus be treated (i.e., restricted) like other forms of direct-to-consumer drug promotion.

Forms of Drug Promotion and Their Regulation

In Canada, as in most other developed countries around the world – with the exception of the United States and New Zealand (and there has been some intensive lobbying to relax DTCA regulations in Europe) (Arnold et Oakley, 2013) – DTCA of prescription drugs is heavily restricted by health regulators. Health Canada's regulation of drug marketing permits advertising but does not allow drug manufacturers to present, in the same advertisement, a

drug's benefits, risks, and other scientific claims or commercial information (Mintzes et al., 2009). In the late 1990s, Health Canada relaxed its restrictions by recognizing that industry should be able to disseminate non-promotional drug information and make it broadly accessible to the public (Gardner et al., 2003). Two types of advertising are now permitted: (1) the *reminder* ad, which presents only the drug name but not its indication, and (2) the *help-seeking* ad, which presents only the medical condition but not a drug or company name and encourages patients to consult their doctor for further information. According to Advertising Standards Canada (ASC), the reminder ad is a permissible form of DTCA, while the help-seeking ad is better labeled as direct-to-consumer information (DTCI). ASC is one of two independent organizations – alongside the Pharmaceutical Advertising Advisory Board (PAAB), whose scope is limited to the material provided to health care professionals (HCPs) – mandated by Health Canada to oversee the application of *Food and Drugs Act* provisions regarding drug promotion. But ASC's control is also limited because its remit is only over promotional activities directed at HCPs; it provides nonbinding recommendations regarding DTCA and DTCI materials submitted on a voluntary basis by pharmaceutical companies.

DTCI can be promoted through three types of media: (1) brochures and websites, (2) help-seeking advertising, and (3) social media (Advertising Standards Canada, 2011). For each of these, the DTCI's sponsor must comply with a set of requirements, most of which are neutral and procedural (e.g., only authorized products can be promoted, only factual information can be used, and visual aspects must be different from related DTCA). Other requirements are more ambiguous, leading to interpretation and possible circumvention, as in ASC's general definition of DTCI: "So, to ensure that your material is indeed 'information' (i.e., non-promotional) and not 'advertising' (i.e., promotional), no element can directly or indirectly promote the sale of a drug" (Advertising Standards Canada, 2011, p. 2). This definition is ambiguous and vague, particularly when one considers the commercial motivations behind a DTCI message. For companies, drug promotion is about orienting patients toward the drug's gatekeepers, that is, to encourage patients to consult their doctor in order for them to obtain a prescription to treat a condition. Also, it is important to recognize that DTCI is usually part of a broad, multilayered marketing campaign (e.g., including reminder ads, HCP-oriented activities or materials, press releases, media coverage) to promote a new drug or a new indication for an existing drug (Cetel,

2012; Ofek et Sarvary, 2003). DTCI thus aims at creating general disease awareness (e.g., about symptoms and associated health risks) and encouraging patients to ask their doctor about whether they might have the medical condition.

An Example of Direct-to-Consumer Information in Action

In order to have a better grasp of DTCI and its implications for health policy, it is helpful to work through a specific example of a drug promotion campaign in a particular national context. As of fall 2012, one of the most prominent drug promotion campaigns in Canada is for erectile dysfunction (ED). Several means are used by the sponsor, Eli Lilly (manufacturer of Cialis®), to reach out to the Canadian population. A *help-seeking* television ad presents the medical condition and the burdens of living with ED, and a website called "40over40.ca" provides access to more information about treatment options. The website presents, in much more detail than the TV ad, the medical condition and its possible causes, the symptoms, and the treatments available and also encourages patients to seek medical help (Eli Lilly Canada Inc., 2011). The whole campaign is designed to fit under Health Canada's policy regarding the distinction between advertising and other informational activities, something that is also highlighted by the presence of ASC's compliance logo on the website alongside those of the Canadian Urological Association, the Réseau de médecine sexuelle du Québec (Québec's Network of Sexual Medicine), and Aboutmen.ca (Men's Health Initiative of British Columbia). The symbolic power of the ASC and other logos can help pass the message that the website is non-promotional, not considered an advertisement, and so the content is reliable (e.g., truthful, not misleading).

The campaign has been reviewed by ASC and recognized as compliant with current Canadian regulations, so the campaign's sponsor, Eli Lilly, cannot be blamed for deploying promotional strategies that one might feel are problematic. The current Canadian policies, which make a distinction between DTCA and DTCI, create an incentive for the sponsor to use these different mechanisms to promote its products. But some noticeable elements in the ED campaign demonstrate that there are important limitations in the Canadian requirements or at least with the way that they are currently applied.

First, while factual statements are required by ASC and Health Canada, the main theme of the campaign – ”40over40” – is not clearly justified. This message is supposed to mean that 40 percent of men over 40 years of age suffer from some degree of ED. While this is quite a good marketing claim, its scientific rationale is problematic: The claim is not visibly supported on the website by references to the scientific literature, and the only information is an estimate that two million to three million Canadians have an ED condition (Eli Lilly Canada Inc., 2011). Moreover, 40over40 conveys the message that a “nonoptimal” erectile functionality is pathologic and so needs to be treated. A subtle and indirect performance threshold (i.e., “optimal” erectile function) is being presented that is linked to popular but scientifically unfounded views of normalcy and aging (I. R. Jones et Higgs, 2010; Marshall, 2010). Specifically, the message is that while younger men are not likely to have problems with their sexual function, men older than 40 can and even should expect to have problems obtaining or maintaining an erection.

The consequences of this shift from what is considered normal to abnormal function are particularly obvious in the “Self-Assessment Quiz” presented on the 40over40.ca website (see Table 1), which encourages patients to consult a physician if their result is lower than the defined “abnormal” threshold (i.e., lower than 22 points out of 25) (Eli Lilly Canada Inc., 2014).

Table 1. ‘40over40’ Self-Assessment Quiz (Questions, Answers and Weighting) (Eli Lilly Canada Inc., 2014)

Take this self-assessment quiz to find out if you may have ED			
#	**Questions**	**Answers**	**Points**
1	*How do you rate your confidence that you can get and keep an erection?*	*Very low*	1
		Low	2
		Moderate	3
		High	4
		Very high	5
2	*When you had erections with sexual stimulation, how often were your erections hard enough for penetration?*	*No sexual activity*	0
		Almost never or never	1
		A few times (much less than half the time)	2

		Sometimes (almost half the time)	3
		Most times (much more than half the time)	4
		Almost always or always	5
3	*During sexual intercourse, how often were you able to maintain your erections after your penetrated your partner?*	*Did not attempt intercourse*	0
		Almost never or never	1
		A few times (much less than half the time)	2
		Sometimes (almost half the time)	3
		Most times (much more than half the time)	4
		Almost always or always	5
4	*During sexual intercourse, how difficult was it to maintain your erection to completion of intercourse?*	*Did not attempt intercourse*	0
		Extremely Difficult	1
		Very Difficult	2
		Difficult	3
		Slightly Difficult	4
		Not Difficult	5
5	*When you attempted intercourse, how often was it satisfactory for you?*	*Did not attempt intercourse*	0
		Almost never or never	1
		A few times (much less than half the time)	2
		Sometimes (almost half the time)	3
		Most times (much more than half the time)	4
		Almost always or always	5

Second, as recommended by ASC's guidelines (i.e., separating disease information and the name of the drug or manufacturer), the sponsor's identity in the ED campaign is not at all obvious. Viewers of the website need to be attentive and look under the "Privacy Statement," "Terms and Conditions," "Disclaimer," "Copyright," or "Accessibility" sections at the bottom of the page, which are in the smallest font and thus the least noticeable content on the website. The issue is that the campaign is an *industry* – and not a *government*-sponsored public health awareness or information activity. Providing clear details about the sponsor's identity would likely help people: (1) critically assess the general message being conveyed by the campaign, (2) evaluate the specific information presented and its relevance to their particular health needs, and (3) judge the credibility of the information provider. Yet, the very policies that were supposedly designed to protect the public from potentially manipulative DTCA in fact discourage or even prohibit industry sponsors from being transparent about their identity, with

the result that it may be very difficult to distinguish between an industry-sponsored DTCI marketing campaign and a government-sponsored public health campaign.

Third, one of the requirements for a campaign to be considered non-promotional is that there be a balance between the treatment presented (e.g., drug and nondrug options) and that a particular drug not be overemphasized. In the 40over40 case, some of the visual design favors the sponsor's drug, Cialis®, which is presented in first place (Option A) at the top of the page in the "Treatment Options" section and has twice as much space (two columns) as any other treatment option (e.g., other ED drugs, pumps, or injections). There is no non-promotional rationale behind this ranking. Cialis® is the first drug presented and the only treatment to hold more than one indication, making it apparently more versatile and potent than the other drugs. Further, the non-oral options, which are presented much further down on the page, are surgical or require a fairly complex apparatus to be inserted into or used on the penis and thus are clearly much less desirable (e.g., "Involves drawing blood into the penis," "Involves the surgical insertion of a prosthesis"); there is no presentation of psychosocial options, such as sexual counseling or psychotherapy. Interestingly, the two tables (for the oral and non-oral options) present differently the rare side effects and contraindications: The table for the oral options uses a different shading, making the side effects and contraindications seem not even part of the table, while with regard to the non-oral options all of the side effects and contraindications have the same shading as the rest of the table. The website's visual aspect thus reinforces in the viewer's mind (1) the benefits of drug therapy in general over other options and (2) the sponsor's drug, which is arguably the primary objective of this promotional campaign.

Despite these problems with the DTCI campaign for ED, ASC judged that the 40over40 campaign was compliant with its guidelines and that the information and its presentation were non-promotional. The line is thus very thin and flexible between what is accepted as non-promotional by ASC and Health Canada's core requirement that in non-promotional activities "no emphasis is placed on one drug product" (Health Canada, 2005, p. iii). Table 2 presents our analysis of the case in light of *The Distinction Between Advertising and Other Activities*, Health Canada's guidance document (Health Canada, 2005).

Table 2. Considerations for determining whether an activity is promotional (advertising) or non-promotional (informational), based on The Distinction between Advertising and Other Activities (DAOA) (Health Canada, 2005)

Considerations	DAOA Test	Case Specificities	Most Probable Case Activity Type
What is the context in which the message is disseminated?	Is it a science-based message delivered [by an expert] or is it a product-related message delivered to a group [...] with a limited agenda?	Message via television ads and website; same as for Public Health campaign.	Either Promotional or Non-Promotional
Who are the primary and secondary audiences?	Where they are different, the message to the secondary audience is more likely to be advertising.	Due to its wide TV and Internet diffusion, audience is mass market; same as for Public Health campaign.	Either Promotional or Non-Promotional
Who delivers the message (the provider)?	Where delivered by an independent party, the message is less likely to be considered as advertising.	Drug Sponsor through TV spots and website.	Mostly promotional
Who sponsors the message and how?	Where any fee is paid by the manufacturer to have the message disseminated, it is more likely to be advertising.	Drug Sponsor, but not overly visible.	Promotional
What influence does a drug manufacturer have on the message content?	Where the drug manufacturer exerts influence (e.g., preparing, editing) on the message content, it is more likely to be advertising.	Drug Sponsor is responsible for all the content.	Promotional
What is the content of the message?	Can the message withstand a test for scientific rigour? Is the information set in an appropriate context, e.g., a discussion of disease management, scientific research?	Scientific rigour is vague or deficient; treatment-oriented rather than disease prevention or management.	Mostly promotional
With what frequency is the message delivered?	Where the same message is delivered repeatedly, the message is more likely to be considered as advertising.	Frequency determined by the Sponsor and limited only by Sponsor's marketing budget.	Promotional

Following the Health Canada guidance regarding advertising, our analysis shows that most considerations point toward the 40over40 campaign as being promotional and not purely informational. But as the Health Canada (2005, p. 3) document clearly states: "No one factor in itself will determine whether or not a particular message is advertising". We can thus assume that the nuance here is that the 40over40 campaign has been identified as non-promotional because it promotes a variety of drug treatments rather than only the sponsor's drug.

Familiarization Through Direct-to-Consumer Information

The effectiveness of DTCI campaigns depends on both the content of the message and how it is conveyed through the mass media, and as with most advertising campaigns, DTCI has as its goal to habituate the public/consumers to accept a certain realty as being true and relevant for them (Belch et Belch, 2008). In being presented as an informational message, DTCI can build consumer confidence and increase the credibility and thus the persuasive effect of the message (Briñol, Petty et Tormala, 2004), a process that we call *familiarization*.

There are subtle ways that a well-designed DTCI campaign can familiarize the public with a particular condition and so influence subsequent information- and treatment-seeking behavior. Specifically, in making informational activities (i.e., help-seeking ads) part of a large, multilayered campaign that includes promotional activities (i.e., reminder ads), a drug sponsor can:

1) build general awareness about a particular disease being an important public health problem;
2) convince a diverse audience that they may suffer from a specific disease (i.e., have related symptoms) and so should consult their physician;
3) suggest that solutions to health problems are best addressed by medical (i.e., pharmacological) treatments, even if the general content of a campaign is disease-related as required by Health Canada (2005) – and this is where the bias is particularly subtle, reinforcing what some scholars have called "pharmaceuticalization" (Bell et Figert, 2012) that Abraham defines as "the process by which social, behavioral or bodily conditions are treated, or deemed to be in need of treatment/intervention, with pharmaceuticals by physicians, patients, or both" (Abraham, 2010, p. 604);
4) direct viewers to consider drugs as a better option than other treatments (e.g., pills over pumps and injections, no mention of counseling or psychotherapy);
5) orient the viewer to a specific drug (e.g., the sponsor's drug may have as much detail as other drugs but be presented first) so that patients can then request a prescription from their physicians (Limbu et Torres, 2009); and
6) hide commercial interests by downplaying the sponsor's identity, because even if *no emphasis should be placed on one drug* (an ASC requirement), viewers can reasonably

be expected to have difficulty in differentiating the DTCI campaign from a government-sponsored public health campaign.

To summarize, a DTCI campaign can provide information about a medical condition that is defined in such a way that the pharmaceutical treatment is seen as the best solution; patients come for information and stay for the pharmaceutical treatment. But only the necessity of seeking medical treatment is conveyed in DTCI; the benefits and the risks of a drug are often vague or even absent. Underlying familiarization is another process in marketing called *evaluative conditioning*, which can induce people to create or reinforce beliefs that a certain drug is the best/only solution to a medical condition (Biegler et Vargas, 2013), even when clinical research may show that effective treatment requires a combination of approaches (e.g., pharmacological and psychosocial) (Althof, 2006; Berry, 2013; Waldinger, 2008).

Parallels can be made with the literature on DTCA, both in terms of the issues raised and also the fact that proponents and detractors do not share the same vision about the influences and consequences of drug advertising and promotion. On one side, proponents of DTCA argue that it informs patients of available treatments and empowers them to seek help and weigh options (Hollon, 1999; Holmer, 1999; Peyrot et al., 1998; Wong-Rieger, 2009). On the other side, opponents of DTCA have argued that: (1) advertisements affect patient discourse, making patients more inclined to discuss the advertisements they have seen than the condition they might have (Hughes-Morgan et al., 2010); (2) DTCA has a harmful impact on the patient–physician relationship (Peyrot et al., 1998; Stange, 2007); and (3) patients would be less insistent if they were more aware of the risks, thereby reducing attractiveness of drug treatments induced by DTCA (Karlowicz, 2009). Arguably, the same debate applies to DTCI, as it is a way to transmit information to patients to help them better assess their needs and understand their symptoms, but it also has the potential to influence or shape certain behaviors. Whether in DTCI or in DTCA, we agree with those scholars who argue that the information contained in drug promotion is not sufficient for – and may even undermine – peoples' ability to make an informed choice about a treatment (Atkin et Beltramini, 2007; Kessler et Levy, 2007).

Misconception as an Active Mechanism

Within a multilayered campaign such as 40over40, each element has its own effect on consumers, and familiarization is triggered by repetitive advertising such as television spots, whether they are reminder ads or help-seeking ads. Consumers may be passive recipients of information when watching TV, but if reference to the disease incites them to visit the 40over40 website, then they have become active seekers of information; it is through this multiple exposure that consumers can become habituated or familiarized with the product. Such familiarity can, we suggest, open the door to a type of therapeutic misconception (TM) among consumers.

A concept developed in research ethics with regard to clinical trials, Henderson and colleagues (2007, p. 1736) explain that TM: "exists when individuals do not understand that the defining purpose of clinical research is to produce generalizable knowledge, regardless of whether the subjects enrolled in the trial may potentially benefit from the intervention under study or from other aspects of the clinical trial."

TM thus involves a potentially very problematic misunderstanding on the part of a patient/research participant regarding the scope of a physician/researcher's professional activity (e.g., both clinical and researcher roles) and expectations about receiving treatment that is in the patient's best interest. That is, patients may foreground their physician's duty to act in their best interest and so assume that they were recruited into the study because it will help in treating their condition or that, in the context of a randomized-controlled trial, they will nonetheless receive the active drug. TM jeopardizes a patient's ability to give voluntary informed consent to participate in a clinical study and so must be mitigated, for example, by separating the physician/researcher role in recruitment and information provision.

In the context of DTCI, we argue that a similar therapeutic misconception can occur when consumers see DTCI campaigns as well-intentioned mechanisms for raising public awareness about an important health condition and disseminating scientifically valid information about appropriate treatment options. As consumers are already habituated to official government public health campaigns that aim to promote and encourage particular behaviors deemed to be

in the public's interest (e.g., smoking cessation, exercise), consumers may fail to see the commercial interests behind the DTCI campaign – and which may not be the same as the consumer's interest – that justify a company's significant financial investment. Because DTCI is required by Canadian regulation to be free from apparent links between disease/medical condition and therapeutic options, a form of TM is arguably fostered.

Well-designed DTCI campaigns exploit patients' trust in medical science and the health care system, misconceptions about disease incidence and risks/benefits of drugs, and legitimate desires to find appropriate treatments for conditions to which they have become sensitized. In this case, TM is triggered by consumers' interest in finding more information about their condition (or that of family members) and possible treatments, so their apparent free and voluntary engagement (watching the TV ads and seeking more information online) blinds them to other information – e.g., risk information, the identity and nature of the sponsor – that would be necessary to critically assess the value and veracity of the message. As has been argued in the case of research (Cunningham et Iyer, 2005), it is not sufficient to rely on individual autonomy or to argue that people simply need to be more media-savvy (although such critical capacities are important); it is up to clinicians, researchers, industry, and government to create a context that will make TM less likely so that the *information* component in DTCI lives up to its name, that is, the information is neutral and unbiased and so enables consumers to freely choose.

As Canadian DTCI regulations require the sponsor's identity to be hidden or at least not be used in a promotional fashion, they also hide the commercial marketing aspect of DTCI and thus the motivations behind the message. Without the explicit connection between the message conveyed and the sponsor's commercial interests, consumers are less able to resist the power of the messages advanced in campaigns such as 40over40 and so will likely associate a certain pill as the solution to their symptoms, regardless of the other factors that may be involved in their condition. As a result, the process of familiarization and eventual therapeutic misconception on the part of the general public becomes hard to counter, something that is completely opposite to the spirit of the health policies and regulations that were supposed to control direct-to-consumer activities involving pharmaceutical drugs.

Conclusion

Direct-to-consumer information can have an important – and, we argue, problematic – impact on patients' imaginary and expectations, but the situation is complex and those responsible are not necessarily the usual suspects. In particular, the pharmaceutical industry, which has legitimately been subject to much critique with regard to DTCA, is not solely to blame in the context of DTCI in Canada. After all, pharmaceutical companies are only playing within the rules set by Health Canada, since the latter relaxed its policies and delegated much of its authority to third-parties (ASC and the PAAB) who have limited coercive power regarding drug advertising. Clearly, the message from government has been that DTCI is both a legal and an approved means to advertise indirectly, by reinforcing a message conveyed by other activities in a multilayered media campaign (e.g., TV ads, disease-related websites, pharmaceutical representative visits to physicians). Regulators should instead acknowledge that DTCI is an effective way for industry to meet its promotional objectives and is a form of direct-to-consumer *indirect* advertising (DTCIA) that builds familiarization and entrenches patients in therapeutic misconceptions.

Even if the case and specific regulations presented here are Canadian, the implications of DTCIA have a much wider impact. In fact, every country that has a partial or total prohibition on DTCA (i.e., every developed country with the exception of the United States and New Zealand) may face the same situation experienced in Canada, whether or not they have explicit DTCI policies. The solutions to the problems associated with DTCIA, and especially the potential for TM, are multiple. But lessons can be learned from analyses of consumer perspectives and the experience with research ethics. Regulation and guidelines need to be implemented to address actual direct-to-consumer activities, ensuring better disclosure of the interests underlying informational campaigns, reducing the risk of and scope for misinterpretation, and thus fostering consumer understanding and informed choice. More generally, the development of comprehensive and reliable sources of health information (i.e., additional information from health agencies and academia) and the requirement that agencies (such as ASC in Canada) verify the scientific rigor of claims in DTCI could help in

disseminating a broader range of scientific evidence about the benefits, adverse effects, and appropriate uses of pharmaceutical drugs. Unfortunately, this is exactly what the current DTCI regulations in Canada are designed *not to* do.

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Regulating Direct-to-Consumer Drug Information: A Case Study of Eli Lilly's Canadian 40over40 Erectile Dysfunction Campaign

Bélisle-Pipon, J.-C. & Williams-Jones, B. (2015b). Regulating Direct-to-Consumer Drug Information: A Case Study of Eli Lilly's Canadian 40over40 Erectile Dysfunction Campaign. *Healthcare Policy | Politiques de Santé*, 10(4), 16-23. doi:10.12927/hcpol.2015.24209

Abstract

Like most jurisdictions, Canada prohibits direct-to-consumer advertising (DTCA) of prescribed drugs. However, direct-to-consumer information (DTCI) is permitted, allowing companies to inform the public about medical conditions. An analysis of Eli Lilly's *40over40* promotion campaign for erectile dysfunction (ED), which included a quiz on ED, shows that DTCI, like DTCA, can be an effective means of drug familiarization. The pharmaceutical industry is "playing by the rules" currently in effect in Canada. Regulators should thus seriously consider whether existing rules permitting DTCI actually meet stated objectives of protecting the public from marketing (i.e., DTCA) that may deliver misleading information.

Introduction

For decades, access to and use of prescription drugs has been controlled by health professionals, and almost exclusively physicians. It is widely recognized that, due to their potency and potential harms, many drugs should be available only by prescription, i.e., their use authorised by and made available to patients under the supervision of a physician (Donohue, 2006). Most developed countries have implemented legislation to control how drugs are developed and marketed to the public (Carter, 1999; Rosenthal, Berndt, Donohue, Frank et Epstein, 2002), because prescription drugs should not be marketed like other commodities.

In the Canadian context, as in most jurisdictions (the United States and New Zealand being notable exceptions), direct-to-consumer advertising (DTCA) of prescription drugs is prohibited because of important concerns about patients misunderstanding a drug's benefits/risks, thereby contributing to potential misuse, specifically: increased demand by patients (Findlay, 2001) and pressure on physicians (Lurie, 2009) to prescribe marketed drugs (usually brand-name drugs), and thus increasing pressure on the budgets of health insurers (public or private) (Mintzes et al., 2003). The Canadian *Food and Drugs Act* prohibits the use of promotional activities and advertising that includes "false, misleading or deceptive" information, and also restricts drug

promoters from "mak[ing] any representation other than with respect to the brand name, proper name, common name, price and quantity of the drug" (*Food and Drugs Act*, 2013).[31]

However, Canadian regulation has undergone a series of reforms that have allowed the pharmaceutical industry to employ other strategies to promote their products (Gardner et al., 2003; Lexchin, 2013). Termed "direct-to-consumer information" (DTCI) by Advertising Standards Canada (ASC)[32], informational campaigns – which may include brochures and websites, help-seeking announcements (e.g., TV spots) and social media – are permitted in Canada when the putative aim is to raise awareness about a particular medical condition and available treatments, but this information cannot mention a specific product or manufacturer (Advertising Standards Canada, 2011). This distinction between non-permitted "advertisement" and permissible "information" is based on provisions in the Health Canada policy, *The Distinction Between Advertising and Other Activities*, which "recognizes the importance to the pharmaceutical industry and to the general public of being able to disseminate and access non-promotional information regarding drugs for human use" (Health Canada, 2005).

When assessing the impact of particular marketing strategies on peoples' perspectives and knowledge about available treatment options, attention to purpose and business context (e.g., competitor drugs or treatments are on the market) is also important when regulators try to distinguish between *advertising* and the more ambiguous concept of *promotion.* Both advertising and promotion are ways to increase customer attention towards and sales of a product (Canadian Marketing Association, 2013), and may be used to present or reinforce a product's image (e.g., as *the* gold standard treatment) and/or a corporate brand (Leiss et al., 2013). However, there is a fine line between the two concepts. Rather than being treated as advertising, i.e., "Any paid form of non-personal communication about an organization,

[31] Unfortunately, as Lexchin and Mintzes (2014) demonstrate, there are important weaknesses in the enforcement of Canadian DTCA regulation, most notably with regard to the promotion of "off-label" uses, financial inducements to use a product, fear-generating advertisements, and advertising of products with serious safety concerns.

[32] Advertising Standards Canada (ASC) is one of two independent organizations (the other being the Pharmaceutical Advertising Advisory Board, PAAB) mandated by Health Canada to oversee the application of Food and Drugs Act provisions regarding drug promotion. However, ASC's mandate is limited to materials submitted on a voluntary basis by pharmaceutical companies and it can only provide non-binding recommendations.

product, service, or idea by an identified sponsor" (Alexander, 1965, p. 9), we suggest that DTCI – with its multifaceted design – lies more in the realm of promotion, i.e., "The coordination of all seller-initiated efforts to set up channels of information and persuasion to sell goods and services or to promote an idea" (Belch et Belch, 2008).

Considering that, in terms of regulation, the ASC is responsible for framing Health Canada provisions on drug-related communication activities, it is pertinent to use their distinction between DTCI and DTCA in order to better understand how DTCI works in practice under current Canadian regulation, and then to evaluate whether this distinction is valid (i.e., whether DTCI is in fact free from the problems associated with DTCA). To facilitate this analysis, we examine Eli Lilly's *40over40* DTCI campaign about the problem of Erectile Dysfunction. We conclude that this campaign – and DTCI in general – can be a very effective and subtle means of building public familiarization with a particular product (e.g., *Cialis*®), and so raises most if not all of the same concerns that led governments to restrict DTCA.

Direct-to-consumer information in action: Eli Lilly's *40over40* campaign

In 2010, Eli Lilly launched *40over40,* a Canadian DTCI campaign for Erectile Dysfunction (ED) to promote its drug *Cialis*®. The campaign complied with Canadian drug marketing legislation and was certified by the ASC. A *help-seeking* television advertisement presented the medical condition, the burdens of living with ED, and referred viewers to the "40over40.ca" website for more information about treatment options. Among an array of information about ED and possible treatments, one of the main features of the website was a quiz that men could take to evaluate if they were among the 40% of Canadian men over 40 years old supposedly with an ED condition (i.e., a good marketing claim that is not adequately referenced on the *40over40* website).

The quiz is a shorter version of the *International Index of Erectile Function (IIEF) Questionnaire*, that was "designed to provide sensitive and specific outcome assessments in clinical trials of ED [with the goal to] develop a self-administered questionnaire that would be suitable for use by clinicians and researchers" (Rosen et al., 1997, p. 823). The *40over40* campaign used a modified version of the IIEF, a self-assessment quiz for patients (Cappelleri et

Rosen, 2005). After five general and non-contextualized questions (each scored out of five), if a man's score is lower than 22 out of 25 points he is identified as being in need of treatment for ED. Interestingly, if he answers "No sexual activity" to the second question "When you had erections with sexual stimulation, how often were your erections hard enough for penetration?", or selects "Did not attempt intercourse" to any of the three next questions, he loses all the points related to that question, thereby placing him in a category considered as abnormal and thus requiring treatment. No matter the context of or the reasons for a lack of sexual function or activity, the website and quiz reports that this is likely due to a problem of ED that can and should be treated. Further, whether or not the score reaches the "abnormal" threshold, the same general statement is presented to the viewer:

> If your score is 21 or lower, you may want to speak with your doctor. Only your doctor can confirm if you have ED, so talk to him or her about these results. If you do have ED, remember that you're not alone. There's no need to worry or feel embarrassed. ED is a very common condition affecting about 40% of men over 40 years of age. Luckily, there are many available treatments to consider, and up to 95% of ED cases can be treated. Learn about your options and then make an appointment to discuss them with your doctor. (Eli Lilly Canada Inc., 2014)

The quiz's form and presentation give the impression that it is a standard clinical evaluation, but without any empirical justification to support its claims or the need for respondents to seek medical advice. Overall, due to logical shortcuts (e.g., that no sexual activity necessarily implies ED) and lack of references, the scientific validity and trustworthiness of the tool is questionable. But the intent is clear: to convince men that, no matter their situation (i.e., their score on the quiz), they should still talk to their physician about ED and seek treatment.

The business context of drug familiarization

The business context of a drug information campaign can be an important factor in familiarizing the public with a drug, an element that current legislation is unable to take into account. To continue with the *40over40* example, *Cialis*® has dominated Canadian public media in recent years, with a noted increase in its media presence (e.g., TV, websites, social media) compared with a significant decrease for *Viagra*®. In part, this can be explained by the fact that:

1) *Viagra*® is a slightly older drug and so is marketed less than more recently commercialized drugs (Wienke, 2005);

2) There is a general absence of advertising from the other competitors, Bayer and GlaxoSmithKline, mostly due to recent market saturation and lack of features to differentiate their drugs from the market leaders, *Cialis*® and *Viagra*® (Dawar, 2013);
3) Pfizer (makers of *Viagra*®) lost its Canadian patent two years before its legal expiration in 2014, following a Supreme Court of Canada decision that voided the patent due to a lack of disclosure in the original patent application of the actual compound treating ED (*Teva Canada Ltd. v. Pfizer Canada Inc.*, 2012). This likely dampened Pfizer's interest in marketing *Viagra*®.

As a result, *Cialis*® is the only product being actively promoted for ED in Canada, which may subtly orient people to think of this drug as the gold standard treatment, rather than considering alternative drugs or non-medical interventions. So even if the stated (and government approved) purpose of the *40over40* campaign is help-seeking, questions should be raised by the ASC as to whether this campaign is not *too effective* at achieving this goal, i.e., that it may be very effective at familiarizing the population with a particular and one-sided view of a condition, in terms of severity, incidence and treatment options. For example, there is evidence that drugs are not the sole effective treatment of ED, and that improvement in erective function is possible through a risk reduction approach (S. A. Martin et al., 2014) and behaviour modification, such as choosing more healthy lifestyles, addressing the comorbidities of ageing, stress reduction, or seeking counselling or psychotherapy. But this evidence is not presented in the information campaign, and so viewers are left with a limited array of possible treatment options, of which drugs are favoured (Bélisle-Pipon et Williams-Jones, 2015a).

The impact of familiarization

Even with the limited amount of information permitted in DTCI campaigns in Canada, they can thus still be a very effective and subtle means of familiarizing the public with a prescription drug, a disease or a company. Further, the public may be unable to evaluate the veracity of advertised claims, especially when the apparent purpose of the marketing campaign is to inform. Familiarization is particularly effective in an era where patients are increasingly seen – and may see themselves – as consumers of health services (Featherstone, 2010), and where

pharmaceutical drugs are seen as commodities (Cohen, McCubbin, Collin et Pérodeau, 2001). Because they are familiarized with a specific drug, consumers of medical information may develop misconceptions with regards to the nature of their medical condition (e.g., incidence, severity) and the benefits and (lack of) risks of drugs (or other products) promoted to treat the condition (Bélisle-Pipon et Williams-Jones, 2015a). Such misconceptions may be especially problematic in the case of ED, with drugs such as *Cialis*® and *Viagra*® having a highly symbolic role in the collective imagination.

Interestingly, Canada is not the only jurisdiction that struggles with regulating DTCI-like activities; for instance, the Netherlands has similar dispositions allowing disease awareness campaigns that are framed by a self-regulated agency. A study from Leonardo Alves and colleagues (2014) demonstrated that there is low compliance with self-regulation guidelines in Netherlands. Even if their study was focused on the print media, the authors raised questions about the growing interest for online drug information and the importance of evaluating "the content and quality of disease awareness websites" in order to determine the effect on consumer behaviour (Leonardo Alves et al., 2014, p. 8).

In the same vein, while assessing a low testosterone unbranded online campaign in the USA, Schwartz and Woloshin (2013) identified three familiarization strategies that can also be found in the *40over40* campaign: lowering the bar for diagnosis (e.g., by using an exaggerated abnormal threshold in the ED self-assessed quiz), overemphasis of the risks to push patients to consult their doctor (e.g., by exaggerating the potential consequences of ED), and orienting interpretations of the evidence about drug benefits and harms (e.g., by emphasizing drug functioning rather than other potential options to address the causes of the disorder, such as stress reduction). These strategies have a significant familiarizing effect, because they are integral to "well-coordinated campaigns [that] are more subtle than drug-specific campaigns, and they blur the line between public health or professional education and marketing" (Schwartz & Woloshin, 2013, p. 1461).

Conclusion

It is important to note that pharmaceutical companies engaged in DTCI in Canada, such as Eli Lilly in its *40over40* marketing campaign for ED, are playing by the rules set by Health Canada. So if the goal of health regulators is to mitigate the potential undue influence created by drug advertisement (i.e., current restrictions on DTCA), then regulators should acknowledge that DTCI raises similar ethical problems as DTCA. They should protect the public from activities that have a familiarizing component that undermines the ability of people (i.e., patients and health professionals) to make free and informed decisions about how to best manage and find treatments for particular medical conditions. More specifically, regulators should consider treating DTCI as an *indirect* but powerful form of advertising that can familiarize people with certain drugs, and so apply similar restrictions to DTCI as for DTCA. Rather than DTCI being treated as a self-regulated activity, and thus only subject to voluntary evaluation by Advertising Standards Canada, information campaigns should be assessed under the current and more strict (if still limited) regulation for DTCA. Also, the business context should be considered when a campaign is assessed so that a non-promotional campaign does not end up promoting one drug as the gold standard. In so doing, regulators could eliminate important ambiguities surrounding the notion of DTCI as being relatively neutral "information provision" and close important loopholes in current regulations.

Recognizing that DTCI is very often drug promotion – in the sense of the World Health Organization (1988, p. 5) definition, where "'promotion' refers to all informational and persuasive activities by manufacturers and distributors, the effect of which is to induce the prescription, supply, purchase and/or use of medicinal drugs" – and thus an indirect form of advertising means that it should be regulated alongside DTCA activities more generally. This would, we suggest, help to make the "rules of the game" for drug marketing more clear and more robust, and also better protect the public and help professionals from initiatives designed to subtly influence their behaviour.

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Using Social Media to Sell Prescription Drugs

Bélisle-Pipon, J.-C. & Birko, S. (2017). Using Social Media to Sell Prescription Drugs. *Impact Ethics* Feb. 9. (https://impactethics.ca/2017/02/09/using-social-media-to-sell-prescription-drugs

Abstract

Jean-Christophe Bélisle-Pipon and Stanislav Birko consider how unregulated forms of direct-to-consumer marketing of prescription drugs using social media might be prevented by amending Canada's Food and Drug Regulations.

Commentary

What if Facebook, Instagram, Google+, or Twitter were to send you targeted sales information about prescription drugs that you're already taking, or ones that you have recently researched online? A far-fetched scenario or near reality?

The use of big data is prevalent in marketing practices and it's reasonable to expect the marketers of drugs, such as pharmacy chains and pharmaceutical companies, to try to negotiate access to large datasets of search histories, posts, likes, tweets and geotagged information. Such data could be used to directly target potential customers who have demonstrated an interest in certain prescription drugs.

The most effective and profitable marketing strategy for pharmacies likely would involve targeted messaging to patients for a drug they recently searched on the internet. The goal would be to entice them to fill their prescription somewhere other than their usual pharmacy. Sufficiently important discounts might be required to motivate patients to change pharmacy, despite possible inconvenience (for example, opening a new file, having to travel further, changing habits). On the plus side, taking advantage of the offers could result in interesting savings for patients. Another potentially profitable marketing strategy might involve familiarizing patients with certain prescription drugs (Bélisle-Pipon et Williams-Jones, 2015a) and frequently reminding them of their existence. For the pharmacy, both strategies could represent worthwhile general marketing practices if this gets customers in the door.

To the best of our knowledge, such pharmacy marketing practices don't exist in Canada, nor elsewhere. But, they could be the next step in the evolution of direct-to-consumer communications. Currently, there is nothing to prevent pharmacies in Canada from using such targeted advertising strategies provided the advertisements don't include too much information. According to Article C.01.044 of the Canadian Food and Drug Regulations: "If a person advertises a prescription drug to the general public, the person shall not make any representation other than with respect to the brand name, the proper name, the common name and the price and quantity of the drug" (Government of Canada, 2016).

While the general use of social media for drug promotion may be legal, is it desirable? Targeted direct-to-consumer communications using social media seems like a profitable marketing strategy in a very competitive environment. The worry with such targeted marketing, however, is that it could contribute to an increase in over-medicalization, particularly for persons who do not yet have a prescription for a drug, and who may (wrongly) interpret direct messages as medical advice. In such cases, direct messages would follow the same pattern as most other industry-sponsored campaigns (such as television and print ads), that aim to convince potential consumers that they are in need of a treatment, and that they should talk to their doctor about it.

While direct-to-consumer communications are often justified on the grounds that they empower patients by providing them with useful information, it is important to reflect on the current state of regulation that allows the active (though limited) promotion of prescription drugs. As noted above, it is important to remember that the marketing of prescription medication has been identified as an important driver of over-medicalization as companies seek to maximize the sales of a drug and foster the creation of new consumer markets. Second, advertising prescription medications as if they were no different than snacks, such as chips or beer, inevitably contributes to the commodification of health where medicines are presented as consumer goods rather than products regulated for their therapeutic power and potential undesirable effects. Both goals are at odds with patient information and support for their informed choice.

Providing people with information that only includes the name of the product and its cost, which is all that is currently permitted by law in Canada, does not empower patients, as promised by

direct-to-consumer communications advocates. For its part, the United States Food and Drug Agency (FDA) has released non-binding recommendations for direct-to-consumer communications in social media, and it is currently assessing the risks associated with drug claims in drug promotion through character-space-limited communications (Food and Drug Administration, 2016). As yet, however, there is nothing specific about targeted and geolocalized advertisements to consumers who have demonstrated an interest in a certain product or product class.

To avoid some of the potentially far-reaching problematic consequences of direct-to-consumer communications using social media, it is worth rethinking current regulations in Canada. The goal would be to help avoid consumerist drift and to ensure that the use of social media is appropriate insofar as it provides meaningful information and is not simply another 'familiarization' strategy. An important first step toward this goal would involve amending section C.01.044 of the Food and Drug Regulations to prevent various forms of non-empowering pharmaceutical direct-to-consumer online communications in Canada.

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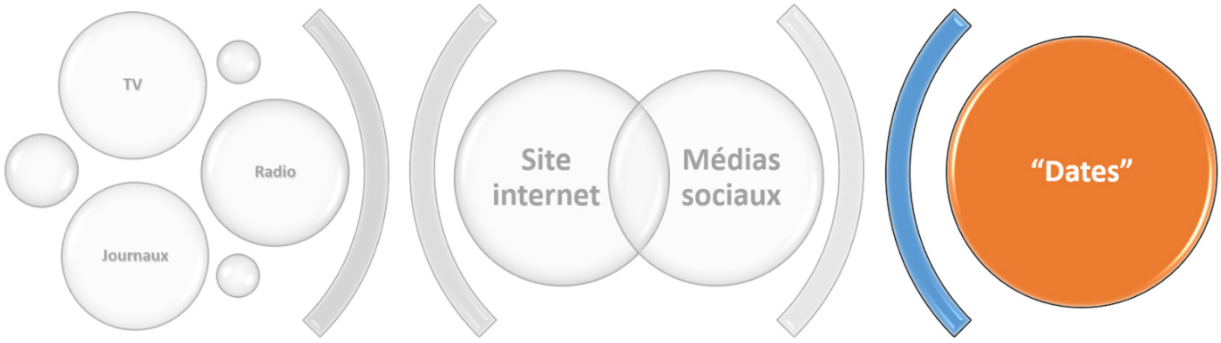
Clarifier les « règles du jeu » pour éviter le contournement de l'esprit de la régulation

Ce chapitre a mis en évidence la mission des régulateurs comme ayant un rôle fort afin de baliser les pratiques et pour établir des « règles du jeu » en ce qui concerne les pratiques acceptables de CDCM. Les cas *40desplusde40* et de l'usage des médias sociaux ont permis de mettre l'accent sur la responsabilité des régulateurs à mieux baliser les pratiques de l'industrie en clarifiant les attentes et les pratiques permissibles. Il a été illustré que la bonification de la régulation est nécessaire pour en clarifier l'esprit afin de s'assurer que les campagnes d'information soient informationnelles et que soit prise en compte le contexte social et de la rhétorique dans l'évaluation de l'acceptabilité et de la légitimité d'une campagne de CDCM.

Une bonification d'autant plus opportune qu'elle devrait mettre à jour des cadres règlementaires, élaborés avant l'apparition et la montée en popularité des médias électroniques et sociaux, afin d'édicter des balises claires et adaptées aux formes électroniques de CDCM. Des balises qui seraient pourtant, selon Gibson (2014), attendues par l'industrie afin d'élaborer des lignes directrices pour mieux autoréguler ses pratiques. À cette actualisation du cadre règlementaire, certaines limites ont été proposées aux pratiques promotionnelles des CDCM afin que les consommateurs reçoivent des informations pertinentes visant à soutenir leur processus décisionnel, plutôt qu'ils soient convaincus sur la base de la rhétorique commerciale et promotionnelle. Constat, également présent dans le précédant chapitre, qui est conçu comme fondamental à l'acceptabilité des CDCM et qui devraient être au cœur de la mission des agences règlementaires.

En ciblant les pratiques et le rôle des régulateurs, l'objectif de ce chapitre n'est pas tant de déresponsabiliser l'industrie que d'insister sur le rôle-clé des régulateurs qui ont une responsabilité fiduciaire envers la population. Dans le contexte actuel, où les agences règlementaires ne sont pas dotées des moyens leur permettant d'assumer leurs responsabilités – notamment Santé Canada qui est chroniquement sous-financés et n'a pas le personnel pour encadrer et surveiller les pratiques de l'industrie (Lexchin, 2016) – il convient de remettre à l'agenda des gouvernements, l'importance de politiques proactives quant aux balises imposées aux pratiques de l'industrie et plus spécifiquement à policer le marketing pharmaceutique.

Chapitre 5. Les communications de proximité



Alors que les cas précédents portaient sur des dispositifs marketing impliquant un médium qui établissait une certaine distance entre la compagnie et le consommateur, ce dernier rempart a été récemment franchi. Alors que les relations fabricant-consommateur ont toujours impliqué un intermédiaire (professionnels de la santé) ou une interface (médias traditionnels, médias sociaux), le marketing pharmaceutique a désormais lieu en présentiel. Cela permet une interactivité inégalée, permettant des interactions plus fluides entre consommateurs et représentants pharmaceutiques (incluant les leaders d'opinion rémunérés par l'industrie). Ce qui est particulier avec ce type de communications est l'absence de toute forme de mécanismes de contrôle et de surveillance entre les actions de l'expert et du client réalisées hors de l'espace public (les annonces télévisées, les sites web ou les messages sur les réseaux sociaux laissent des traces). Comme tout autre dispositif de CDCM, l'objectif putatif demeure d'outiller et d'informer les consommateurs (ainsi que leur famille et leurs proches) sur leur maladie et sur de nouveaux produits disponibles. Le cas suivant soulèvera donc la question de savoir si c'est l'industrie a également ce rôle d'information dans le cas d'interactions en présentiel entre représentants pharmaceutiques et consommateurs. S'en suivra une discussion sur les mécanismes pour réguler cette pratique qui n'a pas reçu l'attention des agences gouvernementales ni encore fait l'objet de directives réglementaires.

Le chapitre est constitué de l'article « *Dating Patients: Wrong for Doctors but Acceptable for Drug Companies?* », sous presse au *Harvard Public Health Review*. J'ai écrit l'article. Bryn Williams-Jones a eu l'amabilité de faire une révision linguistique et a commenté sur

l'argumentaire de l'article. L'article a été présenté lors du Colloque étudiant 2016 des Programmes de bioéthique ainsi que sous forme d'une affiche scientifique au 13e World Congress of Bioethics (Edinburgh, UK) de l'International Association of Bioethics. Il a été primé par le MH Poster Price (premier prix au concours d'affiche) (Bélisle-Pipon, 2016a).

Dating Patients: Wrong for Doctors but Acceptable for Drug Companies?

Bélisle-Pipon, J.-C. Dating Patients: Wrong for Doctors but Acceptable for Drug Companies? Soumis à *Health Politics, Policy & Law*

Introduction

"Over the past year I've received five or six such invitations... In addition to dinner, the format includes a talk with a Q&A by a local neurologist, who I assume is being paid by the drug company to participate in the event" (Richardson, 2015).

Would you like to be invited on a date with a pharmaceutical representative? The date would likely focus on your disease, involve other patients and industry key opinion leaders, and could lead to more if there is chemistry between you and a certain drug. Would you prefer that such a date take place at a fast food chain or at a fancy restaurant? Would you like to hear more about the drug you are taking or maybe about other alternative treatments for your disease?

These are some of the questions that Jennifer Richardson, a multiple sclerosis (MS) patient presents in an article detailing her experiences with a patient support program offered by the company that produces her MS drug (Richardson, 2015). Richardson uses the word "date" to describe the invitations that pharmaceutical companies send to current or prospective patients who already or might soon use their drugs. The purpose of the invitation is clear: "while couched in the language of general outreach to MS patients, the presumed outcome is to get more people signed up to take [their drug]." (Richardson, 2015) Richardson's use of a dating metaphor raises interesting questions about the relationships that a pharmaceutical company can or should develop with its customers, and whether and how such practices should be regulated.

In this article, I analyze such ethical issues and suggest a means to monitor and supervise direct interactions between pharmaceutical companies and patients. I recommend that national governments mandate transparency regarding pharmaceutical commercial interests and launch national organizations and programs to cultivate and regulate patient education activities regarding pharmaceutical products so that patients can make more informed choices to manage their health and well-being. Further, these organizations and programs should be protected from

industry interests to ensure that patients have access to credible and validated information and support.

The Problem

Pharmaceutical industry codes of ethics focus primarily on industry relationships with healthcare professionals (PhRMA, 2009) and patient organizations (PhRMA, 2012). There is no guidance addressing the relationships that industry representatives have with individual patients.

As in Richardson's experience, industry sponsored events for patients tend to focus on the presentation of the merits of a specific drug. In discussions over a meal paid for by the company, pharmaceutical representatives tell patients and their relatives about the benefits of their company's drugs (Richardson, 2015). A medical specialist uses "a drug company-scripted PowerPoint presentation [that] anyone could have given," thereby making it clear that he is restricting himself to the content that has been pre-approved by the company. Afterwards, a company spokesperson presents how she manages her own medical condition using the company's medication (Richardson, 2015). The event is also an opportunity for company representatives to directly interact with prospective customers.

From the development of a drug to its use by patients, responsibilities are fragmented and shared between the various actors involved. Research, development and marketing are the responsibility of companies; evaluation, approval and surveillance of drugs are the responsibility of government; and prescribing and monitoring are the responsibility of health care provider (Bélisle-Pipon, 2013). Personal interactions are largely restricted to provider-patient relationships. Companies do communicate with patients via different advertising and promotional activities, but these are most often not specific to individuals. This raises an important question: do drug companies have a social duty (and legitimacy) to directly inform and educate patients?

In every industrialized country except the United States and New Zealand, direct-to-consumer advertising is restricted and even prohibited due to concerns about the negative consequences of industry influence on patient and health care provider behavior (e.g., disease-mongering,

over-prescription). Even regulated direct-to-consumer information (DTCI) activities – informational messages disseminated through media such as TV spots, websites, brochures, or newspapers – can be a source of concern (Bélisle-Pipon et Williams-Jones, 2015b). DTCI, in most jurisdictions around the world, may not be transparent about the source of the informational message, i.e., that it is coming from a corporate sponsor rather than a government public health agency, thus obscuring the potential commercial interests underlying the message. Commercial messages that raise awareness about a particular health condition aim to familiarize the public with a condition or drug and thus influence subsequent treatment-seeking behavior (Bélisle-Pipon et Williams-Jones, 2015a). This drug familiarization effect can then trigger therapeutic misconceptions among patients. "Therapeutic misconception" is a concept taken from research ethics where patients misinterpret the dual role of their physician during clinical trials: as clinicians, they are trying to improve their patients' health, as researchers they seek to produce generalizable knowledge which will not necessarily benefits their current patients. Reapplying the concept to DTCI (Bélisle-Pipon et Williams-Jones, 2015a), patients' familiarization with a certain drug may lead to them having misconceptions about disease incidence and the risks/benefits of drugs, while also having legitimate desires to find appropriate treatments for conditions to which they have become sensitized through DTCI.

Whether the companies have good or bad intentions and whether or not patients are aware of the underlying commercial interests, there is a risk for conflicts of interest that "may exploit the vulnerability of the patient...and ultimately may be detrimental to the patient's well-being" (AMA, 2014). Nonetheless, patients may suspect that their participation is being instrumentalized by pharmaceutical companies in order to drive the sale of the drug; and so as Richardson's reflection shows, there is a major problem, both in terms of the perceptions that patients may have about "dates", as well as aim of the companies organizing these the "dates" (Richardson, 2015).

The Solution

Self-Regulation

Considering that conflicts of interest linked to the pharmaceutical industry are already controversial (e.g., paid scientific expert panels and gifts to physicians) and have undermined

the industry's reputation, it is all the more important for companies to demonstrate responsible behavior. This requires self-regulation to limit direct encounters with patients, either by pharmaceutical companies themselves or by their national associations (e.g., PhRMA in the USA, Innovative Medicines Canada, LEEM in France). In being proactive, the industry would place itself on the moral high ground by demonstrating the capacity for "policing its own members to ensure they abide by the guidelines that govern their behaviors", while also avoiding the threat of more stringent government regulation (Katsanis, 2016, p. 129).

However, in certain circumstances, self-regulation will be helpful but may not be sufficient. In situations where they are in a position of being both judge and judged without the recourse of an impartial third-party (as in the case with "dates"), then self-regulation is clearly insufficient. It is expected that the industry will behave in a responsible matter and police its own practices, but the establishment of guidelines and rules must come from an authority that is not in a conflict of interest (i.e. having the opportunity to turn an activity into increased products sales).

Government Regulation

Company "dates" with patients must also be regulated by the government, as are encounters between health care providers and patients. Government regulation could ensure that no adverse event, therapeutic misconception or undue influence resulting from direct patient-company interaction unjustifiably affects patients.

1. Mandating Transparency

In the case of "dates" between companies and patients, it is important that the commercial sponsor's identity be transparent rather than hidden behind the smokescreen of supposedly independent patient-interest groups (Hughes et Williams-Jones, 2013). Disclosing the financial and organizational links between patient-oriented events and the companies that sponsor them is one way to make evident the potential conflicts of interest, so that patients (and others) are able to more critically evaluate the medical information they receive and make better informed decisions. In fact, mandatory transparency is becoming an increasingly common way to minimize potential biases related to financial conflicts of interest (Institute of Medicine, 2009). The US Physician Payments Sunshine Act, for example, requires that companies publicly

disclose annual payments and gifts to physicians and teaching hospitals starting with as little as $10. However, an annual declaration alone is insufficient to eliminate bias; without other mechanisms, transparency can simply have the effect of shifting "the problem from one of 'secrecy of bias' to 'openness of bias'" (Krimsky, 2010, p. 89).

Although there is intense scrutiny into manufacturer-physician relationships and corporate sponsorships, there are no equivalent initiatives to the Sunshine Act to deal with industry-patient relationships. It stands to reason that as for medical education, transparency should be compulsory for the financing and facilitation of educational and informational activities directly targeting patients. Without such transparency, it is not possible to even assess the magnitude and the scope of commercial influences over patients-oriented activities.

2. Regulating Patient Medical Education

To ensure that patient medical education (PME) is independent from – and thus not influenced by – commercial interests, national governments would have to pass legislation allowing agencies such as Health Canada and the FDA to regulate PME activities. These agencies could then delegate responsibility to independent non-governmental organizations (NGOs) that set standards, and review and license industry sponsored patient education activities. But these para-public organisations would need stable and adequate funding if they are to avoid corporate capture (Bélisle-Pipon et Williams-Jones, 2016).

3. Licensing Patient Medical Education

For such NGOs to be publicly credible entities, they must also be sufficiently independent from government in order to be insulated from political disputes (e.g., changes in government) and economic turmoil (e.g., budget cutting in the context of deficits). Further, to carry out their role of licensing and surveillance, they must ensure the inclusion of a plurality of perspectives – i.e., diverse publics, with no focus on industry interests – in their development of sound and relevant standards that are based on the best available evidence regarding patient needs (and socio-cultural contexts). The governance structures of these NGOs should include as members a variety of stakeholders, notably health administrators, healthcare professionals, researchers (e.g., in health policy, the social sciences, bioethics), and patients. To participate, members must

be clearly independent from both industry and government, and this requires robust conflict of interest policies and procedures to ensure that any interests (e.g., individual, institutional, political and financial) do not take precedence over the provision of trustworthy and independent information and education for patients.

In their operation and assessment of PME, the NGOs would need to take into account specific socio-cultural contexts, including the environment in which the PMEs occur (e.g., differences in healthcare systems, DCTI regulation, availability and costs of treatments). Further, in a context of globalized access to drug information made possible by the Internet, some form of international harmonization of PME standards is warranted to ensure that there are no extreme differences from one jurisdiction to another (i.e., coordinated licensing of international activities or those offered simultaneously in several jurisdictions).

In terms of functioning, the national NGOs would independently assess the content and structure of PME programs to ensure that they will achieve clear educational objectives. Organizations such as pharmaceutical companies, patient groups, or universities that wish to provide PME activities would need to receive pre-approval (such as in the form of a license) from the applicable national NGO on the basis of established standards and robust surveillance, to ensure that PMEs are not simply another form of industry-funded DTCI. Based on the history and regulatory experiences of CME activities (Barnes, 2017; Eggertson, 2016), additional attention should be paid when funding comes from industry, or even if there are suspicions as to where the funds may come from; industry interests should not bias educational outcomes. In case of misconduct or breaches of the licensing requirements, organizations should be sanctioned, ranging from reprimand and monetary fines to the temporary or permanent prohibition of delinquent institutions and groups from conducting PME activities.

A PME activity licensing assessment would thus ensure that PME activities: 1) do not advocate for one particular drug; 2) are not a way for companies to diversify their promotional channels (e.g., no overt corporate branding, gifts, one-sided messaging); and 3) are independently provided and evaluated. Regulatory bodies would need to evaluate PME programs on the basis of the stated educational objectives, as well as any contextual factors external to PME activities

(e.g., reduced competition in a specific drug marketing environment, increased public sensitivity – receptive or stigmatizing – for a specific condition) that might unduly influence patients. In addition to helping to avoid problematic conflicts of interests, patient participation would have to be voluntary, and not associated with conditional benefits, such as improved access to drugs or reductions in co-payments. Further, the PME's content must be clear and its format not replicate an advertising campaign. So evaluations should ask participants questions such as: did they learn more about their disease? Did they learn more about symptoms management? Were specific treatments presented, and if so, how many? Was there a balanced presentation of benefits and risks? Did participants learn how to improve their global health beyond the medical condition for which they are taking a certain medication, and how to change their lifestyle for health improvement (e.g., by modifying their physical activity, nutrition, stress management, and healthy habits)? Did they receive financial incentives to participate to PME activities? Was the venue adequate for such event? Appropriate answers to these questions would then provide confidence that in the PME, patient-expert encounters are designed to address patient needs and not simply promote one specific drug or a class of drugs. Participant evaluation can contribute to detailing the content and context, far beyond what is described in the official program, and to assist in *a posteriori* evaluations of the relevance, utility and independence of a particular activity. Such evaluation certainly has inherent limitations; however, Richardson's vivid account is exemplary in showing that the perception of participants makes it possible to pinpoint important issues about the validity of such events. Additional mechanisms should also be implemented to periodically assess and monitor organizational practices for PME license renewal.

To ensure that these ethical considerations are taken into account by all national NGOs, it is important that standards are consistent from country to country, much like harmonized standards for clinical trials, which were first implemented in some countries and have subsequently become international. One might even imagine an international authority to facilitate collaboration among national NGOs, so that PME evaluation and regulation standards are optimal and reflect the constant evolution of PME, and also ensure that the NGOs tasked with oversight are credible and have the means to fulfill their mission.

Conclusion

Given the difficulty that many patients face in accessing health information – that they can understand – about the nature of their condition/symptoms and how best to manage them, it is not surprising to see the deployment of new forms of PME. But in this context, it is essential that patients be empowered through access to independent sources of information, and not through unregulated industry-sponsored direct patient interactions. This calls for the restriction of certain forms of promotional practices, specifically all forms of direct interactions. Rather than being invited on "dates", as described by Richardson (Richardson, 2015), that seek to woo patients to use a particular sponsor's drug, patients should be provided with balanced and credible information so that they can make informed decisions about how best to manage their health. In light of the evident conflicts of interest, regulators should acknowledge that pharmaceutical representatives and companies are not the best suited to directly support patients in their decision making. Indeed, regulators should define explicitly – and legally constrain – the nature and scope of PMEs, and then ensure that appropriate independent oversight structures (the aforementioned NGOs) are implemented and funded to conduct PME monitoring and evaluation. Such evaluation should also be mandatory rather than voluntary (a criticism made of current DTCI regulations) and cater to patients' instead of industry interests. All these conditions are necessary to ensure that there is an effective alternative to direct interactions between companies and patients, and that PMEs fulfill their mission of providing information, awareness and empowerment, and prevent drug familiarization and therapeutic misconception that undermine patient autonomy and decision making.

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Reconnaître une limite formelle : l'industrie n'est pas la mieux placer pour éduquer les consommateurs

Les interactions directes entre représentants de l'industrie et des consommateurs est un thème qui demeure encore trop peu étudié. Ses enjeux éthiques sont d'ailleurs complètement absents du radar des régulateurs. Pourtant, ce type de communication sans interface médiatrice (comme un diffuseur télévisé ou une plate-forme électronique), offre un espace où les consommateurs sont fortement exposés aux influences de l'industrie. Revêtant une apparence et une volonté putative d'éducation des patients sur leur condition de santé, sur la gestion de leurs symptômes et sur les traitements disponibles, l'industrie cherche à se substituer au rôle traditionnel des professionnels de la santé. Ceci leur permet de tabler sur les avantages de la communication directe auprès des consommateurs qui est reconnue comme plus efficaces à générer des ventes qu'à travers le recours à des intermédiaires (Park, 2017).

Il transparaît ainsi dans chacun des cas présentés, cette tension entre les visées commerciales, les attentes pro-sociales et les meilleures pratiques pour réguler les CDCM. Il convient de rappeler que, selon Mintzes (2009), chaque dollar investi en marketing se traduit en quatre dollars de ventes de produit. L'industrie semble ainsi avoir bien plus intérêt à valoriser les moyens lui permettant d'arriver à ses fins de profitabilité, en continuant d'utiliser des dispositifs de CDCM à fort impact de ventes (incluant au travers d'une rhétorique valorisant la désirabilité de la solution pharmaceutique), et d'utiliser plusieurs dispositifs de sorte à rejoindre les consommateurs par plus d'un type de CDCM (Narayanan, Desiraju et Chintagunta, 2004).

De plus, étant particulièrement intéressée à mettre de l'avant une solution pharmaceutique comme panacée, l'industrie n'a cependant ni l'indépendance ni la confiance découlant d'une relation fiduciaire et balisée comme celle qu'ont généralement les professionnels de la santé envers leurs patients. Ces cas montrent donc une limite importante aux CDCM : l'industrie ne devrait pas se substituer aux professionnels de la santé, et n'est pas la mieux placée pour éduquer les consommateurs. La trop grande proximité et les interactions non-médiées sont problématiques et ce sont aux régulateurs de mettre en place des balises pour assurer que les « dates » n'aient pas cours; mais ils devraient également assurer un rôle proactif dans la mise en place d'activités d'éducation médicale des patients, servant à la fois de lieu pour informer et

autonomiser les patients, ainsi que de contrepoids aux influences de l'industrie. Autant de dimensions qui illustrent la nécessité de cadres règlementaires et d'incitatifs efficaces pour inciter la conformité des pratiques de l'industrie aux attentes (bio)éthiques et pro-sociales.

Alors que la **Partie II** a mis l'accent sur la nécessité de clarifier et d'améliorer les règles du jeu qui doivent guider et encadrer les pratiques de l'industrie (notamment, en prenant en compte l'impact de la rhétorique et du contexte social, en adaptant la régulation aux nouvelles pratiques et aux nouveaux médias, et en imposant des limites quant à la proximité entre l'industrie et les consommateurs et les communications non-médiées), la **Partie III** se concentre, pour sa part, sur l'autorégulation des pratiques de l'industrie. L'ensemble des cas amène au constat que les régulateurs se doivent de mieux assumer leurs responsabilités, mais également que l'industrie se doit d'adopter de meilleures pratiques sur la base de repères éthiques clairs et spécifiques à la pratique du marketing pharmaceutique.

Partie III – Discussion

Les études de cas ont permis de brosser à grands traits le portrait des grands enjeux éthiques qui entourent l'hétérorégulation des principales formes de CDCM. Les considérations liées aux failles de la réponse règlementaire ainsi que la responsabilité des acteurs et le partage de responsabilité entre les régulateurs publics et l'industrie ont aussi été explorées. Comme il a été vu à travers les études de cas, les enjeux éthiques entourant les CDCM sont complexes et ramifiées. Ce dispositif de communication fait appel à un nombre important d'acteurs, au premier rang les consommateurs, les gouvernements, les professionnels de la santé et de façon plus large la société dans son ensemble. Il a été possible à travers ces études de mieux saisir la nature des enjeux éthiques, cerner la responsabilité des principaux acteurs – plus particulièrement celle des gouvernements et des compagnies – ainsi que d'élaborer certaines pistes de solution.

L'ensemble des cas questionne et met au défi la vision classique pro-CDCM qui stipule qu'il est légitime de communiquer directement avec les consommateurs, car cela servirait de vecteurs d'information et d'autonomisation. Néanmoins, les divers cas étudiés tendent à illustrer, tels des pièces d'un casse-tête, que la réalité est toute autre. Le tableau général qui se dessine pointe plutôt vers une réduction de l'information et de l'éventail des choix possibles qui s'offrent aux consommateurs; la solution pharmaceutique semblant toujours plus intéressante, plus attrayante, et parfois la seule réellement présentée. L'éventail des cas semble indiquer que l'autorégulation de l'industrie est essentielle pour parvenir à une meilleure conciliation entre les impératifs de la recherche du profit et les impératifs éthiques portant sur l'information et l'autonomisation des consommateurs ainsi que les attentes pro-sociales.

À partir de cette perspective, la **Partie III** forme la discussion de la thèse et s'organise autour de deux grands axes. D'abord, dans le **Chapitre 6**, une analyse des principaux enjeux éthiques que soulèvent les CDCM sera présentée. Les cas seront analysés sous la lentille des quatre théories morales qui sont souvent considérées comme étant canoniques et qui ont autant eu d'influence en bioéthique qu'en éthique des affaires (Durand, 1999; Moriarty, 2017), soit le

déontologisme, le conséquentialisme, l'éthique de la vertu et le contrat social. L'usage de ces quatre théories morales permet de dégager les dimensions éthiques transversales aux cas, sans enchâsser l'analyse uniquement dans l'un ou l'autre de ces cadres conceptuels et moraux. Synthèse qui devrait permettre de dresser la liste de standards éthiques *a minima* qui doivent être respectés pour une pratique adéquate et moralement acceptable, mais qui tient toutefois compte des impératifs commerciaux inhérents à la logique du secteur pharmaceutique. Ensuite dans le **Chapitre 7**, il sera proposé une énonciation d'une bioéthique pharmaceutique établissant un ensemble de repères bioéthiques ainsi qu'une organisation permettant aux employés de faire de la bioéthique au sein de leurs activités et de les guider pour la prise de décision au sein des départements de marketing des compagnies. Cette proposition cherche à rendre compte et répondre aux besoins d'outils et de soutien auxquels doivent compter les employés afin de concilier, dans leur pratique quotidienne, des impératifs pouvant s'opposer.

Chapitre 6 – Établir des standards pour guider l'éthique du marketing pharmaceutique

Pharmaceutical Marketing Ethics: Establishing Ethical Standards to Support More Acceptable Practices

Bélisle-Pipon, J.-C. et Williams-Jones, B. "Pharmaceutical Marketing Ethics: Establishing Ethical Standards to Support More Acceptable Practices". Soumis à *Ethics, Medicine and Public Health*.

J'ai écrit le premier brouillon de l'article. Bryn Williams-Jones a ensuite révisé l'article et la logique du texte. Nous nous sommes entendus sur la version finale.

Abstract

This paper analyses the major ethical issues raised by direct-to-consumer communications (DTCC) of health products (specifically pharmaceutical drugs), with a view to proposing ethical standards of practice for the marketing profession. A case-based analysis of four types of marketing practices is used to highlight the main ethical dimensions of DTCC. The ethical implications are then unpacked using the specific lenses of prominent ethical theories (consequentialism, deontology, virtue ethics, social contract), so that non-experts in ethics – i.e., marketing professionals – can understand the implications for their daily practice. To synthesize the essential ethical imperatives related to DTCC, an oath for marketing professionals is also offered as a guide to ethical conduct. This application of prominent ethical theories to a case-based analysis of pharmaceutical marketing helps to ground the complex ethical dimensions of DTCC as well as offer possible solutions to support better ethical practices by marketing professionals.

Highlights

- Direct-to-consumer communications (DTCC) of health products are contested marketing practices that have benefited from little in the way of practical ethical standards.

- Ethical theories can help shed light on the complex ethical dimensions of marketing practice.
- Pharmaceutical marketers must be equipped with comprehensible and essential ethical imperatives so that they can behave (and be recognized by the broader public) as professionals.

Keywords: case-based approach; direct-to-consumer; ethical practice; ethical guidance; pharmaceuticals; pharmaceutical marketing

Introduction

"Marketing activities present some of the most discussed and challenging ethical issues in the contemporary world of business" (Palmer, 2017, p. 1028), and those for health products are certainly no exception. If anything, the inherently value-laden nature of health and illness (i.e., hope, fear, desperation, vulnerability, uncertainty) make the consumer marketing of products that are designed to treat illness and improve human health (e.g., pharmaceutical drugs and medical devices) an ethical quagmire. What information is being communicated to patients qua consumers of health products? By whom? Through what means and with what intent? Are consumers able to evaluate, with or without the support of health professionals, the veracity of this information and judge the utility of a marketed product in meeting their own health needs? And are existing regulations to protect consumers adequate? These are but some of the many ethical questions raised by direct-to-consumer communications (DTCC) of health products (Bélisle-Pipon, 2017; D. Harker, 1998).

DTCC includes all forms of communications that companies, most notably in the pharmaceutical sector, use to reach out to consumers.[33] Communicational objectives vary depending on the content conveyed, which may be either promotional (direct-to-consumer advertising, DTCA) or informational (direct-to-consumer information, DTCI), and according to what is allowed by national legislation (Bélisle-Pipon et Williams-Jones, 2015a). DTCA

[33] For the sake of clarity, we will use Mulinari's (2016a) distinction between *advertising*, *promotion* and *marketing*. *Advertising* is the use of a public medium to attract attention to a specific product. *Promotion* is broader and pertains to all activities and practices that seek to increase sales. *Marketing* includes all promotional, scientific and public activities and practices that seek to align products and consumers.

explicitly aims at selling products and is severely restricted (or even prohibited) in every industrialized country, with the exception of the United States and New Zealand, due to concerns about the negative consequences – or harms, according to Biegler and Vargas (2016) – of industry influence on patient and health care provider behaviour (e.g., disease-mongering, over-prescription) (Applbaum, 2006; Mintzes, 2006; Perls et Handelsman, 2015). By contrast, DTCI is permitted in most jurisdictions – notably in Europe, Canada and Australia – so that companies can inform the public about medical conditions.

Both types of DTCC (i.e., DTCA and DTCI) use diverse means to reach consumers, and have evolved along with developments in information technology; the media of DTCC now include television and radio spots, in-print ads, websites and blogs, social media as well as in-person meetings. While classical pharmaceutical DTCC (TV, radio, print) were restricted, due to costs, to those drugs with the most potential to become blockbusters, electronic forms of DTCC now allow the promotion, at low cost, of all kind of drugs, from blockbusters to niche and orphan drugs. The pharmaceutical industry has continued to investment heavily in DTCC (Katsanis, 2016), and while exact data on global promotional expenditures is not available (Eagle et Dahl, 2016), estimates show a net increase over the last two decades in the USA: $US166 million in 1993, $US1.2 billion in 1998, $US4.2 billion in 2005, and $US5.6 billion in 2016 (Biegler et Vargas, 2016; Donohue, 2006; McCaffrey, 2017a). For electronic DTCC alone, in 2016 the industry spent $US2.5 billion, an increase of about 20% since 2013 (Huhmann et Limbu, 2016). Further, given jurisdictional variability regarding what can or cannot be communicated to consumers (i.e., restrictions or prohibitions on DTCA), and the difficulty of implementing effective barriers to communication on the Internet and social media, companies are now able to engage with a global potential consumer base. Consumers have never been so exposed to pharmaceutical DTCC as they are today (Campbell, 2009).

Few would contest the fact that the potency of pharmaceutical drugs, and the associated risks for patients, necessitate monitoring by health professionals, surveillance and oversight by national health regulators, and informed choices by patients as consumers of these products. In the US, for example, since the 1962 *Kefauver-Harris Amendment to the Food, Drug and Cosmetic Act*, pharmaceutical manufacturers have been required to demonstrate the safety and

effectiveness of prescription drugs, and obtain preapproval of their marketing plans (Goodrich, 1963; Hollister, 1974). Discussions about DTCC have thus focused on whether restrictions should be strengthened or loosened, with often heated debate about the moral grounds for and against each position. Does DTCC empower or disempower consumers? To what extent should individual liberty to choose overrides public health concerns? DTCC proponents argue that such prescription drug communication is an important means of responding to the informational needs of consumers, allowing the latter to be more aware and thus make better health care choices (M. Harker et Harker, 2007). Some opponents, however, go so far as to argue that corporate marketing is one of the main negative drivers for decreasing public health (Freudenberg, 2005). And efforts have been made, e.g., in the US, to counter the perceived negative effects of DTCC, through the development of guidelines to assist physicians in mitigating patient exposure to marketing (Sufrin et Ross, 2008).

Given the difficulty that many patients have in obtaining health information (i.e., that is accessible and understandable) about the nature of their condition/symptoms and how best to manage them, it is not surprising to see an increase in consumer health information seeking behaviour (Dahl et Eagle, 2016; M. Harker et Harker, 2007). The popularity of health information websites is now well documented and they continue to proliferate (Katsanis, 2016). But sources are not always the most appropriate (e.g., for the right condition), and finding information that is balanced, unbiased, and understandable may be particularly challenging. By contrast, with its wealth of experience in marketing and significant financial resources (which far surpass those of national health regulators), the pharmaceutical industry is often a very (if not the most) effective actor in communicating information to consumers in a manner that is accessible and understandable. But some would argue that this places the industry in a conflict of interest (Mackenzie, Jordens, Ankeny, McPhee et Kerridge, 2007; Velo et Moretti, 2008), because commercial interests may not necessarily align with patient interests, leading to bias in information provision.

It should not be forgotten, however, that the definition of marketing is “the coordination of all seller initiated efforts to set up channels of information and persuasion in order to sell goods and services or promote an idea” (Belch et Belch, 2008, p. 16). Pharmaceutical advertisements

are designed to “spur demand for the good and therefore boost its producer’s sales and profits” (Campbell, 2009, p. 1) and drug promotion “is a major determinant of prescribing patterns” (Herxheimer et Collier, 1990, p. 310). According to Mintzes (2009), each dollar spent on DTCA generates about $US4.Therefore, it is in the interest of the pharmaceutical industry that DTCC encourages the purchase of their products. And it is precisely on this point that proponents and opponents disagree about the legitimacy and rationale for DTCC.

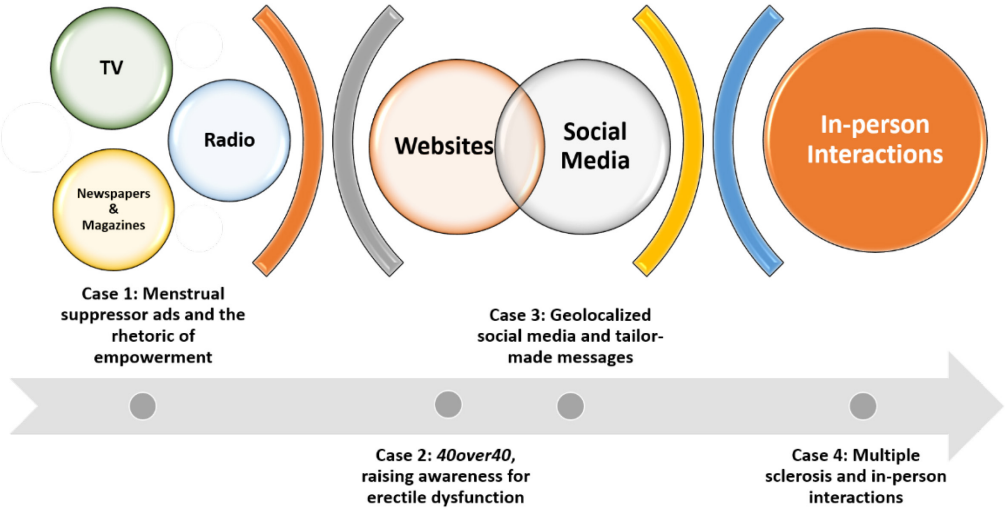
Normative judgments for or against DTCC are often made based on particular claims about the informational and educational dimension of DTCC for consumers. It is therefore necessary to examine the practices used in DTCC to identify the associated ethical issues, and then identify standards with which to evaluate these practices and so formulate normative recommendations with a view to better orienting and framing this practice. As Dunfee and colleagues (1999, p. 14) note, “The need for normative theory to provide guidance in evaluating ethical issues is particularly pressing in marketing”. Yet, a comprehensive ethical analysis of the various forms of DTCC has yet to be conducted, nor is there consensus on what might constitute a framework for the ethical conduct of pharmaceutical marketers (McCaffrey, 2017b).

There is thus arguably a need to draw a broad map of the ethical considerations at stake in pharmaceutical DTCC. But just as business ethics has often been called an oxymoron (J. W. Collins, 1994; Duska, 2000), the very question of whether ethics has its place in marketing has been questioned by some scholars (Beltramini, 2003; Durif, Graf, Chaput, Ducharme et Elbakkali, 2009; Watkins et Hill, 2011), i.e., that marketing is fundamentally immoral or amoral depending on one’s view of the legitimacy of manipulative communication. Leaving aside this debate, we argue that attention should nonetheless be given to the ethical dimensions of DTCC because “medicines promotion control [has] emerged as one of the weakest functions of the pharmaceutical sector.” (Kohler et Baghdadi-Sabeti, 2011, p. 8) This control, which includes both government regulation and self-regulation by industry, intrinsically carries an ethical dimension that is necessary and relevant to unpack.

Four case studies – each pertaining to a particular type of DTCC (see Figure 12) – will be presented briefly, in order to provide a snapshot of pharmaceutical DTCC practices, and the

associated implications and ethics issues. Following these case presentations, the overarching ethical concerns raised by DTCC will be analyzed through the application of a range of moral theories that will each serve, from their distinct perspective and their understanding of the normative, to highlight what should be expected from industry in terms of responsible behaviour, and whether/how DTCC practices can be ethically justified.

Figure 12. Continuum of different forms of direct-to-consumer communications (DTCC)



Choosing one or multiple ethical frameworks or theories with which to analyze pharmaceutical marketing may be somewhat arbitrary. There is obviously an aspect of personal affinity and philosophical position, and it would be hard to make the case that one approach is "better" than another. Nonetheless, the literature on marketing ethics (and business ethics in general), has tended to focus on or deploy four main ethical theories: *consequentialism*, and specifically *utilitarianism*, is usually the main theory used (Nantel et Weeks, 1996); *deontology*, which often serves as a counter-thesis (Hunt et Vitell, 1986); *virtue ethics*, which is used to evaluate the authenticity of marketers' posture and practices (Koehn, 1995); and the social implications of marketing practices, often understood as grounded in the *social contract* linking industry to society (Dunfee et al., 1999).

These theories are rich and complicated, with long histories and debates about their pertinence and application to various questions in moral philosophy and applied ethics. Each could be used

independently to analyse the moral requirements and the social responsibility of corporations, and to reflect on ethical business practices (Dunfee et al., 1999; Murphy, 2010; Nantel et Weeks, 1996). We will not defend one particular approach or enter into debates about their respective strengths and weakness. Instead, following Chakrabarty and Bass (2013), we will combine these four approaches in our ethical analysis of DTCC practices. Each theory will be briefly described (enough to set the table for a discussion) and then will be used to highlight the ethical implications of the cases under examination. The application of these theories provides a means to focus on particularly salient aspects of marketing ethics that can benefit from more detailed analysis and refection. Further, in presenting – in a simple and accessible way – the ethical issues and the benchmarks with which individuals and organizations can make persuasive and reasoned arguments related to DTCC, non-ethics experts in the pharmaceutical industry can better understand the ethical dimensions of DTCC and thus be better placed to participate in a more nuanced discussion about the purpose of drug promotion. By way of conclusion, an oath for pharmaceutical marketers will be proposed that summarizes, in broad terms, what should constitute ethically responsible practices in DTCC. In so doing, we aim to help respond to Laczniak and Murphy's (2006) call for guidelines for normative marketing ethics in the specific context of pharmaceutical drug promotion.

Ethical perspectives

A contextualized discussion of pharmaceutical marketing ethics needs to be built upon a certain understanding and definition of ethics. This is especially true in an area where ethics is not the first language used: that of marketing, efficiency and profitability are much more present within industry discourse. In general, ethics involves (among other things) the analysis of behaviour or conduct to assess its rightfulness, particularly when this may cause benefit or harm to other people. The objective is thus to develop a better understanding of a moral dilemma in order to make normative claims about right or wrong actions. However, there is not a single ethics; on the contrary, ethics is polysemic. Further, classical ethical theories are often each based on different foundations that give varying moral value, priority and weight to different elements: duty, action, conduct, the bond that unites us to others, etc. To illustrate this, four ethical theories will be briefly examined, the classic trio of *consequentialism* (e.g., J.S. Mill, J. Bentham),

deontology (e.g., I. Kant) and *virtue ethics* (Aristotle) as well as *social contract* theories (T. Hobbes, T Scanlon).

The point, here, is not to present a coherent or integrated normative framework that could be used by ethicists to conduct a comprehensive ethical analysis of marketing and DTCC. Instead, the more modest goal is to provide enough ethical benchmarks to help those with minimal or no ethical training deal with the ethical dilemmas or challenges encountered in their professional practice. Presenting these ethical theories in a simple manner does not mean "dumbing down" or ignoring their complexity, nuances and history. Instead, the aim is to show that these theories can be important references for establishing a set of minimum benchmarks that are sufficient to pinpoint the main tensions raised by real cases, thus enabling a more enlightened normative judgment on commercial practices by one of the key stakeholders confronted to them, i.e., marketing professionals.

The selection of theories is made both on the basis of their history (they are literally "the classics" of moral theory) and their use in business ethics (Chakrabarty et Bass, 2013; Hunt et Vitell, 1986; Koehn, 1995). The four theories are frequently used in the literature; however, the way they are used will vary widely. Some authors, such as Hunt and Vitell (1986), use some of these theories in a comparative manner, and argue that a comprehensive understanding of marketing ethics must account for both deontological and consequential aspects. Other authors emphasize the merits of a particular theory, such as focusing on social contracts (Dunfee et al., 1999) or virtue ethics (Williams et Murphy, 1990) as a grounds for marketing ethics. These two approaches are mutually compatible, and may serve to establish the basis on which marketing practices can be evaluated, consistent with Laczniak and Murphy's (1993, p. x) definition of marketing ethics as "the systematic study of how moral standards are applied to marketing decisions, behaviours and institutions".

Consequentialism

Consequentialism is the view that only consequences matter and have values from a normative standpoint. Simpliy put, the moral rightness (and adequacy) of acts or rules depends on their consequences. Motives, decisional context and norms do not carry much moral weight.

Utilitarianism – best known through the works of 19th Century British philosophers, John Stuart Mill and Jeremy Bentham – is an important subset of consequentialism, and considers the ethics of any act or rule based on the principle of utility: an act or rule is morally desirable and expected only if it produces the greatest amount of collective happiness. Conversely, acts or rules are considered wrongful if they result in a decrease in the collective level of happiness (or utility). The moral agent must therefore make choices that will generate the greatest net increase of happiness for all in comparison to available alternatives (by that agent and at the time).

Consequentialism could be used to inform pharmaceutical marketing ethics by assessing the utility of this type of business practice, as well as for taking into account the calculation of net increase in happiness (or utility) generated by DTCC.

Deontology

Deontology is concerned not about what we actually do (and the impact our actions have) or who we are (what virtues inhabit us and guide our actions), but what we *ought to do*. It is the individual's duties that are at stake and on which are assessed the rightfulness of choices made. One of the most well-known versions of deontology is that proposed by the 19th Century German philosopher, Immanuel Kant, which. stands out due to its structure of two types of imperative: hypothetical and categorical. The former involves imperatives relative to one's context and scope of actions, while the latter are universal and unconditional and apply to every moral agent, at all times, and the terms are non-negotiable. A moral agent should follow moral rules that could be generalized to all people. Since every person has dignity and moral worth, one must treat others as an end and never merely as a means. Duty is thus understood as the conformity of actions that must be justified at all times and in all places. That being said, this does not *entail a strong duty of general beneficence, or, if it does, it places a limit on the demands of duty*: everyone should be able to pursue their own projects and have an open future, but there are no binding expectations that agents directly contribute to the realization of other peoples' projects and well-being. In deontology, it is the dutifulness that is most critical.

Deontology could help to define what is a dutiful pharmaceutical marketing practice as well as provide the grounds on which the respect of the person must be fostered.

Virtue Ethics

Where deontology and consequentialism are concerned with the choices and actions of individuals, virtue ethics focuses on moral character. From this perspective, neither the duty nor the consequences of acts have an overarching value. It is rather the excellence of character traits and dispositions of individuals, called virtues (e.g., honesty, generosity, loyalty, justice, mercy, integrity, fairness, trust, respect, empathy, prudence), that make a person morally good. In its classical Greek presentation by Aristotle, an act is virtuous if it is one that a virtuous individual would perform, therefore virtuous individuals are the measure of virtue in action. The virtuous person is also interested in seeing others develop their virtues. Emphasis is placed on the individuals' posture and motive, and not simply on discrete acts, so it is the persistence in time of a virtue that matters; virtues are anchored and reaffirmed through the repetition of virtuous actions over time. And intention is essential: it is not enough for people to base their actions on conformity with a rule or moral expectation, rather they must act for the virtue in itself (being honest for the sake of honesty). A virtuous agent is thus a someone that does the right action, at the right time and for the right reason.

Virtue ethics could help clarify the virtues on which DTCC practices should be based, and so serve as a guide for marketers.

Social Contract

Social contract theories build upon the idea that there exists a hypothetical social contract or pact that unites all the parties involved. As developed by early thinkers such as the 17th Century English philosopher Thomas Hobbes, *contractarianism* is based on mutual self-interest. It recognizes that individuals act in their own interests, but can discipline themselves by recognizing (and negotiating) a limit to the satisfaction of their immediate or short-term interests in order to pursue other long-term interests. Agents must agree and choose rationally to submit to a social regime (a set of rules) that limits their liberties (and polices behaviour) in order to prevent chaos and anarchy (a state more hazardous and harmful to agents). A modern version of *contractualism* proposed by Thomas Scanlon (1998) builds morality on the justifiability of an action. An "act is wrong if its performance under the circumstances would be disallowed by any set of principles for the general regulation of behaviour that no one could reasonably reject

as a basis for informed, unforced, general agreement." (Scanlon, 1998, p. 153) The establishing of moral standards and principles stems from mutual recognition; thus, what is important is the reasonableness of and an agent's motivation, rather than their rationality.

Social contract theory could outline how DTCC practices may be mutually beneficial for the stakeholders involved and help characterize the grounds on which some practices may (or may not) be justifiable.

Summary

The different ethical perspectives provided by the above theories can be useful for understanding how ethics informs DTCC-related issues. Normative claims about DTCC being "good" or "bad" frequently invoke decontextualized arguments that lack substantive ethical foundations. However, by employing the ethical perspectives described above, it is possible to better understand how and why structured ethical reflection about DTCC can help clarify the concerns about DTCC practice and assign responsibility appropriately.

Key ethical concerns for each form of DTCC

Four case studies will be presented to help understand the nature and scope of the key ethical concerns raised by different forms of pharmaceutical DTCC (see Table 3).

Table 3. Summary of DTCC cases and main ethical implications

Case Study	Type of DTCC	Jurisdictions, regulations	Media	Scope	Interactivity	Identified Ethical Concerns
Menstrual Suppressors: rhetoric of empowerment	DTCA	USA Regulated	TV, radio, print ads	Widespread, effecting virtually entire population	*None* • Consumers watch, listen to communications • No direct interaction with sponsors or relatives	• Framed choices • Information emphasizes benefits, minimizes risks • Affect informed choices

"40over40": raising awareness for erectile dysfunction	DTCI	Canada (similar in UK) Regulated	TV, internet, social media	Widespread, effecting virtually entire population	*Low* • Requires consumers to actively search for information, or simply an online presence • Exchanges on social media • Self-diagnostic test	• Information emphasizes benefits, minimizes risks • Drug familiarization and therapeutic misconception • Over-emphasize pharmaceutical solutions
Geolocalized social media	DTCA	Canada Unregulated	Social media	Widespread, effecting virtually entire population	*Moderate* • Exchanges on social media • Targeted ads • Possibility to interact with campaigns' sponsors	• Information presented emphasizes benefits and minimizes risks • Disease-mongering
Multiple Sclerosis: information and education evening	DTCA & DTCI	USA Unregulated	In-person	Targeted, patients already diagnosed with condition	*High* • Interactivity between patients (their families) and pharmaceutical representatives	• Information emphasizes benefits, minimizes risks • Attendance often accompanied by financial benefits • Legitimacy of direct interactions questioned by patients

Case 1: Menstrual suppressor ads that frame consumer choice via a rhetoric of empowerment

Commercialized for over half a century, hormonal contraceptive drugs (HCD) are ubiquitous in Western countries and are now taken by over 200 million women (Junod et Marks, 2002). In addition to their effect on women's emancipation and reproductive autonomy, the success of HCD is partly due to pharmaceutical company advertising efforts that emphasize non-contraceptive dimensions pertaining to women's lifestyles, such as suppressing menstruation (Watkins, 2012).

Since the commercialization of HCD in the late 1950s and early 1960s, drug ads have played an important role in popularizing their use, despite censorship and restrictions on access to HCD products in some countries (Bailey, 2010). Initially, ads were only addressed to physicians through medical journals to raise awareness about the advent of contraceptives. The emphasis was on liberating women from their own biological functions and giving them control over their

bodies. The very first HCD, Enovid, was advertised as “the first fully feminine molecule for cyclic control of ovulation” (« Enovid® », 1962). Following the relaxation of drug promotion regulations in the US in 1990s, companies began to target women directly (Watkins, 2012). This coincided with a shift in advertising campaigns: between the 1960s and 1980s, HCD promotion focused on birth control and family planning, but starting in the 1990s, the focus shifted to lifestyle benefits (such as for treating acne).

Since 2003, extended HCD regime (eHCDr) have been marketed for complete menstrual suppression (MS). The underlying marketing interest stems both from women’s increasing willingness to adopt an eHCDr regimen that significantly reduces or eliminates menstruation (Glasier et al., 2003; Shakespeare et al., 2000; Sulak et al., 2002), and from a recognized added-value in an increasingly saturated market (Mamo et Fosket, 2009). The manufacturers of contraceptive drugs such as Loestrin, Seasonale/Seasonique and Yaz have focused on notions of choice and control; by presenting HCDs as means of empowerment, these ads recount menstrual experiences as a constant fight by women to reconnect with their true identities. MS advertisements promote the positive value of controlling menstrual cycles while downplaying the drugs’ adverse effects and even trivializing their use (Johnston-Robledo et al., 2006; Till, 2015). For instance, in campaigns promoting Seasonique, menstrual periods are presented as “punctuations” or “interruptions” in women’s daily lives that the drug promises to correct (Woods, 2013, p. 268). Campaigns promoting eHCDr to achieve MS talk about “worry-free” use with “fulfillment being ahead”; “Don’t wait another month to discover your possibilities” women are told, because these drugs give a woman a “new choice for her future”.

The rhetoric of these ads focuses on how the drug will fulfill and enhance women’s daily life, with very little mention of the drugs’ risks and possible delays in regaining fertility. The Society for Menstrual Cycle Research (2007) recommended that DTCC better inform women about the risks of eHCDr, especially since it has been shown that advertisements for certain MS medications were blatantly minimizing the risks; Yaz’s manufacturer, Bayer, received a warning letter to this effect (Abrams, 2008). In these ads, no mention is made of the limit of the scientific evidence, and that no studies have been conducted on prolonged use beyond five years despite the fact that women may use these products on a continuous basis for two or three decades. In

addition, some drug promotion identifies all women as being at-risk of having menstrual health problems and thus legitimate subjects for treatment (Johnston-Robledo et al., 2006). On Yaz's website, for example, a self-diagnosis tool was provided to US patients using a "pathologizing checklist for women's emotional and bodily experience of menstruation [and as a] standardization instrument to categorize what is biologically normal and what is not" (Ebeling, 2011, p. 830). The ads, regardless of the specific campaign, play on social and cultural factors (expectations, pressures, social constructs) that frame womanhood and so shape perceptions about available choices. Paradoxically, contraceptives were initially advertised as liberating women by giving them control over their reproduction, but in downplaying the health risks, these contemporary ads limit women's "legitimate" and informed choices.

Case 2: 40over40, raising awareness for erectile dysfunction and promoting a drug

In 2011, Eli Lilly launched the Canadian DTCI campaign, *40over40,* to raise awareness about erectile dysfunction (ED); a similar campaign was launched in 2008 in the UK. The name of the campaign comes from company's statement that 40% of men over 40 years old suffer from erectile dysfunction, to a certain degree. Using multichannel marketing, a help-seeking television ad presented the medical condition and the burdens of living with ED, encouraged men (and their partners) to consider whether they (or their loved one) were at-risk, and to visit the website 40over40.ca for more information. The website presented in much more detail the medical condition and its possible causes, the symptoms, and the treatments available with the recurrent objective of encouraging consumers to seek medical help (Eli Lilly Canada Inc., 2011).

Several elements lead one to conclude that the marketing campaign was not particularly informational or impartial (Bélisle-Pipon et Williams-Jones, 2015a). First, factual statements, such as the main slogan "40over40" and the statistic implying that two to three million Canadians have an ED condition, are not clearly justified nor supported by references to the scientific literature. The campaign medicalizes healthy men by exaggerating the actual numbers of those suffering from ED and by playing on scientifically unfounded views of normalcy and aging (I. R. Jones et Higgs, 2010; Marshall, 2010). In addition to the general content of the campaign, a self-assessment quiz is presented to help viewers assess whether they are suffering from ED. The quiz fosters the medicalization of healthy individuals since it encourages men to

consult their doctor if their result is lower than the abnormal threshold (i.e., lower than 22 points out of 25); the mere fact of not having had sex in the last month means that the person falls below this threshold and is encouraged talking to their doctor about ED.

Eli Lilly, the sponsor of the campaign, is not clearly identified and may not be obvious for most viewers. There is thus a risk that the message is misinterpreted as coming from a government-sponsored public health awareness or information activity, rather than an industry-sponsored publicity campaign. This limits the critical view that consumers can have with regards to the intent of the campaign, and the underlying interests of the sponsor (i.e., to encourage the sale of Cialis).

To inform consumers about available healthcare choices – and for the campaign to be considered non-promotional (i.e., not DTCA) under Canadian regulation – a balanced presentation must be given of the various treatments available (e.g., drug and nondrug options). A particular drug should not be overemphasized and non-pharmaceutical options should not be cast in an unfavourable light. However, in the *40over40* campaign, special attention is given to the drug sold by Eli Lilly, and other treatments such as sexual counselling and psychotherapy are presented in a manner discouraging their use, despite evidence indicating their effectiveness. As a result, consumers may disregard some choices that could very well be beneficial, in favour of a more attractive pharmaceutical solution that is most profitable for the company.

Notwithstanding these concerns, the *40over40* campaign was designed to comply with Health Canada's policy regarding the distinction between prohibited advertising and permitted informational activities. The campaign was approved by Advertising Standards Canada (ASC), a non-governmental organization mandated by Health Canada to oversee the application of *Food and Drugs Act* provisions regarding drug promotion. It is thus worrisome to note how even an approved "information" campaign can be an effective means of familiarizing the public with the scope and benefits of a particular prescription drug (or a class of drugs) and so promote increased consumer demand and a problematic rise in the prescribing and use of medications that may be neither the most appropriate nor the most cost-effective. DTCI campaigns can thus be very efficient means to promote drugs that are appealing to consumers, that can gather public

interest for well-known health conditions (such as ED), and for which a social context is particularly favourable (Bélisle-Pipon et Williams-Jones, 2016).

Yet, with DTCI for ED (and other drugs), the industry is generally playing within the existing rules and regulations set by health regulators. Regulators should thus consider whether existing rules permitting informational messages actually meet their stated objectives of protecting the public from misleading information. And companies should acknowledge that responsible practices are grounded on the proviso that their campaigns genuinely foster consumers' informed choices.

Case 3: Geolocalized social media to target consumers with tailored-made messages

Initially reluctant to use social media to engage with consumers, due in large part to strict national regulations in Europe and Canada, in recent years the pharmaceutical industry has become increasingly present on social media (Wells, 2014). It is estimated that the industry spent about $US350 million on social media in 2015 (Huhmann et Limbu, 2016). Social media allows companies to directly reach a large community of potential consumers, and in a targeted way, by segmenting consumers based on online data collected about browsing habits on sites such as Facebook, Twitter, Instagram, or Google (O'Neil, 2016). Currently limited to messages in the form of advertising banners or to sponsoring Facebook pages or accounts designed to raise awareness about a certain disease (Niquette, 2012), the industry may soon begin to better target their messages by making use of the full potential of social media (i.e., data mining). The next step in the evolution of DTCC could very well be targeted sales information about prescription drugs that consumers are already taking or which they recently searched for online (Bélisle-Pipon et Birko, 2017). The use of Big Data is now widespread in consumer marketing practices, so it is reasonable to expect drug marketers to negotiate access to search histories, posts, likes, tweets and geotagged information, in order to individualise their marketing and so directly target potential customers who have demonstrated an interest in certain prescription drugs, related products or health information.

In Canada, DTCA is restricted, but it is possible to advertise the name of the drug, its price and its quantity if no mention is made about the drug indication (Bélisle-Pipon et Williams-Jones,

2015b). This information is enough for both pharmacy chains and pharmaceutical companies to broaden how they reach out to consumers through social media. For pharmacies, it would represent an effective means to entice consumers, with whom they do not have a commercial relationship, to fill their prescription somewhere other than their usual pharmacy (or to reinforce loyalty with their existing pharmacy). Such a strategy could be a worthwhile general marketing practice for pharmacies if this gets customers through the door. And for the pharmaceutical industry, social media represents a new means to better segment and reach their consumers with tailored-made messages that are all the more convincing because they will be based on the specific personal characteristics (interests, behaviour) of the individuals being targeted.

While the general use of social media for drug promotion may be legal, is it desirable? Targeted DTCC using social media seems like a profitable marketing strategy in a very competitive environment. It is not necessary to have access to information of a medical nature *per se*, nor to the medical record to gather sufficient data; on the contrary, this may even be prohibited by national regulators (Abdelhak, Grostick et Hanken, 2016). But a large set of proxies make it possible to evaluate the degree of an individual's potential interest and so determine what messaging will be most persuasive. The worry with such targeted marketing is that it could further contribute to over-medicalization, particularly for persons who do not yet have a prescription for a drug, and who may (wrongly) interpret direct messages as medical advice. In such cases, direct messages would follow the same pattern as most other industry-sponsored campaigns (such as TV and print ads), that aim to convince potential consumers that they are in need of a specific product, and that they should talk about it with a trusted professional (e.g., their doctor). But in addition to receiving targeted messages, consumers can become (without knowing it) vectors for the dissemination for DTCC content, simply by sharing or commenting on received messages, thus increasing the reach and potential impact of such campaigns.

Case 4: Multiple sclerosis and in-person interactions, when there is no buffer between industry and consumers

In the US, consumers are receiving invitations to attend meetings where they can interact with local medical experts (Bélisle-Pipon, 2017). The purpose of the invitation is generally obvious, even to consumers. According to Richardson (2015), in the context of her experience with

promotion of multiple sclerosis drugs, "while couched in the language of general outreach to…patients, the presumed outcome is to get more people signed up to take [their drug]". Such industry-sponsored events tend to focus on a company-scripted presentation and discussion of the merits of a specific drug, over a meal paid for by the company. These events may be associated with conditional benefits, such as improved access to drugs or reductions in co-payments by consumers for whom the cost is only partially reimbursed by their insurance, as a way to encourage consumers to attend. This represents the most direct interactions that companies can have with consumers. Yet, surprisingly, while there are guidelines for interactions with patient organizations (e.g., to limit corporate capture and mitigate conflicts of interest), there is currently no guidance either from government (regulation) or industry (self-regulation) regarding the relationships that industry representatives can or should have with consumers.

Attendees at these events are not blind to corporate motivations, but may be confused by the fact that similar services could very well have been provided by their healthcare professional (Richardson, 2015). Personal interactions regarding the choice of prescription drugs are largely restricted to the context of physician-patient relationships. Companies do communicate with patients via different advertising and promotional activities, but these are most often not specific to individuals. In-person interactions between consumers and pharmaceutical representatives thus raise interesting ethical questions about the relationships that a pharmaceutical company should develop with its customers, industry's role and responsibility to inform and educate consumers, and how such practices should be regulated. There is an inherent conflict of interest in the industry's dual position of selling products and replacing healthcare professionals who are normally responsible for informing, treating and protecting patients. Whether the companies have good or bad intentions and whether or not patients are aware of the underlying commercial interests, there is a risk that for-profit motives negatively effect the information provided and that patients need to make informed choices to manage their health and well-being.

Applying ethical theories to DTCC issues

On the basis of the four cases presented, a discussion will be made through each of the four ethical theories. This will highlight the main ethical dimensions (see Table 4) that the DTCC raise through the double scope of real cases and ethical theoretical perspectives. This will provide an early response to Laczniak and Murphy's (2006) call as well as establish ad minima ethical guidelines for support more adequate and moral pharmaceutical marketing practices.

Table 4. Four theoretical approaches to the ethics of pharmaceutical marketing

	Consequentialism	Deontology	Virtue Ethics	Social Contract
Core morality	• Consumer satisfaction • Effects of DTCC on population health & well-being	• Practices should be duty-based • DTCC must be informational, empowering	• Consistency between behaviour & virtues • Integrity of the messaging	• Communications and practices must be mutually beneficial & justifiable
Information presentation	• Maximize access to quality information • Consider long-term consequences of behaviours induced by this information	• Individuals as ends in themselves • Messaging must be truthful • Enable informed choices, in person's best interest	• Presented in an honest and diligent manner	• Fair presentation of risks and benefits
Legitimacy of direct interactions	• Acceptable, if an effective way to disseminate unbiased quality information that enables better understanding and informed choices	• Acceptable, if conducted in a dutiful manner, respecting consumers	• Acceptable, if conducted in a way that respects virtues, such as integrity, honesty and benevolence	• Acceptable, if practice is mutually beneficial for all (consumers, healthcare professionals, health system, companies), and publicly accepted
Disease-mongering	• Unacceptable • Negative consequences for individuals, healthcare systems, etc.	• Unacceptable • Manipulative & disrespectful	• Unacceptable • Manipulative & dishonest	• Unacceptable • Breach of trust between stakeholders

Framed choices	• Unacceptable • Negative consequences for individuals, healthcare systems, etc.	• Unacceptable • Manipulative & disrespectful	• Unacceptable • Manipulative & dishonest	• Unacceptable • Breach of trust between stakeholders
Making profits from health	• Profits should not be a reason to generate more harms than utility	• Justifiable, if consumers treated as ends in themselves	• Morally significant, if quest for profit has a positive impact on agent's posture, making them less virtuous	• Justifiable, if mutually beneficial for the company, patients and society

Consequentialism

Arguably, a pharmaceutical company does not have formal duties towards its customers other than to sell safe and effective medicines, and so it is largely the company's prerogative to decide how and to whom to advertise its products (Watkins et Hill, 2011). Interestingly, Nantel and Weeks (1996) recall that a utilitarian standpoint is often the first ethical recourse for reflecting on marketing ethics. Considering that the role of marketing is "to discover and meet consumer needs" (Smith, Goldstein et Johnson, 2013, p. 159), to base the utility and appreciate the consequences of a marketing activity, consumer satisfaction could be viewed as a measurement of the effectiveness and quality of a marketing effort. Thus, the foundational principle on which to ground marketing ethics would be consumer satisfaction (Martin, 1985; Nantel et Weeks, 1996), and could then serve as a benchmark by which to assess the impact of DTCC. That being said, ethical analysis built solely on consumer satisfaction will end up with an ethical myopia: short-term satisfaction being much more valued and praised by marketing (Singer, Lysonski, Singer et Hayes, 1991). Thus, if reapplied to industries having an impact on human health (such as DTCC), the scenario ends up as follows: "in the short term, a need is satisfied which, in the long term, is obtained at the price of the health of customers" (Nantel et Weeks, 1996, p. 13). It is therefore important to go beyond the mere perception of consumers, and consider a much more comprehensive calculation of utility.

A thorough calculus of DTCC utility would require weighing treatment-seeking behaviours as well as resulting pleasures. It is necessary to consider how a certain DTCC informs and engages untreated consumers in developing a need for the drug so that they obtain an adequate treatment

as compared to the false positives generated by advertising (i.e., consumers with no medical need taking a drug, and who believe the drug is right for them). From a consequentialist perspective, the industry's primary motivation – profitability – will have no particular influence on the ethical assessment of DTCC practices as long as the calculus is that DTCC generates more utility than harm. However, consumers should not only be seen as disincarnated entities to whom companies offer and promote a range of products. Drugs can have (positive and negative) major consequences for peoples' lives, so the utility calculation must be sufficiently complete to account for what is necessary for a DTCC to be effective and produce an optimal impact on collective utility.

Utility and satisfaction of pleasures must therefore be appreciated in a more sophisticated way, and include ad-generated expectations, long-term implications for consumers as well as consequences for their relatives and for the broader healthcare system (e.g., increased use of services, costs for insurers). Certain campaigns might be addressed to more vulnerable populations, such as drugs for life-threatening conditions, where communications might overemphasize expectations (e.g., improvements in quality of life or life expectancy) while downplaying associated risks or concerns. Special attention must also be given to lifestyle drugs, such as for erectile dysfunction and menstrual suppressors, where the commercial success of these drugs lies not only with consumer needs, but also in the much larger market of healthy consumers. In addition to the pleasures of consumers (gain and loss in terms of health and well-being), the calculation must also take into account the social dimension. For instance, when marketing encourages patients to change to a new generation drug when their current drug is working well, it leads to higher costs for the system (for third-payers and out-of-pocket for consumers) (Brody et Light, 2011), which may not be cost-effective and not very utility-friendly.

New means of communication, such as social media, allow for a segmenting of the consumer market and the direct targeting of individuals with messages tailored to their profile (e.g., based on data gathered about social media behaviour). In the case of DTCC for menstrual suppression, it could mean segmenting the population between: 1) women who would be more inclined to accept a rhetoric of emancipation through the use of certain drugs, 2) those seeking convenience

(decreasing the frequency of their menstrual bleeding), 3) those who want to treat their acne and 4) ultimately those who suffer from dysmenorrhea and endometriosis. It is possible for a company to adapt its message to cluster (or segment) the consumer market, and to present the benefits and risks in a way that makes the drug appealing for the target population. Social media may be very effective in adapting the promotional message to resonate with the characteristics of particular consumers, and to foster a certain view of consumer satisfaction, but not if it ends up convincing a healthy population to talk to their doctors in order to be prescribed with a drug that is not medically required or for which the risks outweigh the benefits.

Obviously, accurately anticipating the consequences of a practice and calculating its impact (or utility) on consumers can be an exceedingly complicated endeavour. So it can be a significant challenge for marketers to attempt to analyze and forecast unknowable future events (Dunfee et al., 1999). However, the idea to be retained here is the notion of impact (and probability of impact) of DTCC on consumers. This can be summarized by the following two tests, adapted from Laczniak and Murphy (1993): 1) The *consequences test*. Is it likely that any major harms to consumers, their relatives or to society will result from a certain contemplated marketing practice? 2) The *utilitarian test*. Is there a salient and satisfactory alternative action to the proposed marketing practice that produces equal or greater benefits to the affected parties? These tests can help marketers to question the implications of their practices, by looking at the consequences.

Deontology

Although consequentialism is more often referred to when evaluating the morality of a business based on the consequences of their actions, Martin (1985) indicates that deontological ethics can also be a fertile and relevant ground for a marketing ethics. Nantel and Weeks (1996) even argue that a duty-based approach is much more relevant than utilitarianism as an ethical guide for marketing decisions.

Fundamentally, the duty of marketers – as stipulated by the current rationale for DTCC – is to provide reliable information that is useful to consumers. Dutifulness commands that a legitimate practice efficiently inform and empower consumers. Another way of defining duty in marketing

is to derive it from the definition of marketing as promulgated by the American Marketing Association (2013): "Marketing is the activity, set of institutions, and processes for creating, communicating, delivering, and exchanging offerings that have value for customers, clients, partners, and society at large." A dutiful practice would thus be valuable to customers and society (along with third parties who have a role in the conduct of the affairs of the company). Marketing must provide a meaningful contribution to these stakeholders, so there should be no reason for anyone to feel wronged by marketing practices. A third way of founding duty in marketing is by the companies themselves. Companies develop self-enacted and self-imposed codes of conduct in which consumer interest is commonly a foundational concern. These codes are deontological in nature and call for the compliance of practices that adhere to guiding principles and rules of conduct. However, they should not be the only devices through which to appreciate the duty and compliance with the duties of companies, because codes are of limited efficacy (Robin, Giallourakis, David et Moritz, 1989).

While industry may not have a direct duty to consumers in the way that health professionals have towards their patients, the pharmaceutical industry develops products that are particular in the sense that they have a direct impact on a medical need. This involves a set of (negative) duties that are distinct from the marketing of conventional mass consumption products. It is thus possible to summarise pharmaceutical marketing duty as involving the provision of accurate and reliable information to an audience that may need a particular health product (e.g., medical necessity). It is reasonable, then, to expect that the information conveyed will respond to the information and empowerment needs of consumers. As such, pharmaceutical marketing should avoid creating undue needs or fears on the part of consumers (disease-mongering or the use of pathologizing and misleading quizzes), as such practices would be contrary to duty.

The Kantian idea of expecting the respect of autonomy of others to be a priority implies that consumers (receptors of communication) must be treated as ends in themselves; and this is key issue in DTCC. One of the important categorical imperatives in the Kantian perspective is truth. One must always be truthful, even if that may have adverse consequences (for the agent or anyone else). The imperative is very appropriate with regards to marketing which is the practice of disseminating to potential consumers information that promote the use of a product. Truth is

key to a dutiful (i.e., ethical) marketing practice; any form of exaggeration or falsification of the truth is therefore to be avoided. The fact is that much pharmaceutical marketing seems to frame information for an end that is to sell drugs, and not to ensure of facilitate consumer autonomy. Pharmaceutical rhetoric should not have the effect of closing down available choices with misleading information – which is what the emphasis on pharmaceutical solutions eventually leads to – but of supporting informed and autonomous decision making.

In unmediated marketing practices (i.e., in-person or via social media), the objective is to transform consumers' (and their relatives) personal activities into a vector for the promotion of medicines. For example, in the above case study about multiple sclerosis and in-person interactions, Richardson questions whether the company actually believed that a paid meal would be enough to turn it into "unpaid evangelist for their drug" (Richardson, 2015). As Niquette (2010) points out, the objective of the companies is twofold: it is necessary to succeed in building confidence while exploiting the bonds of friendship for purely commercial ends. Once the confidence has been acquired, consumers will relay the messages to their loved ones, to those around them and to the members of their networks. Therefore, consumers act as content distribution vectors of the companies, because the consumers' loved ones will have much more confidence in their recommendations than in the marketing of a drug manufacturer.

The advantage of campaigns with a high degree of interactivity is the participation of individuals. Social media would not be such a popular success were it not for the active participation of individuals in sharing their experiences, commenting on threads of discussion and relaying information. Both social media and face-to-face interactions rely on the participation of Internet users as a relay for messages (i.e., promotional vectors), stimulating their network's commitment to certain products or specific (promotion or informational) campaigns.

On the basis of the primary motivation of industry, i.e., making profit, one can argue that the primary obligation of marketers is contractual and towards their employer; so, in acting in accordance to their duty, marketers would have to make sure that they promote and increase sales. There is a key dilemma between two conflicting duties: an immediate duty towards their

company and a remote duty towards consumers. However, making profits is not inherently beneficial for consumers, and should not be a sufficient and necessary foundation for dutiful marketing behaviors and practices. To be ethical, from a deontological perspective, two categorical imperatives could be established: 1) no communication may knowingly mislead consumers either about scientific facts, benefits or adverse events, and 2) DTCC must respect and foster peoples' autonomy, which is the very justification for the acceptability of DTCC. DTCC practices not respecting the autonomy of people and that treat consumers as a means to an end to further the organization's self-interest would therefore be condemned and judged unacceptable. A practice is thus potentially deontologically legitimate if, at a minimum, it respects these two imperatives.

This further implies that any practice that frames (intentionally or not) consumer choices is necessarily wrong. Therefore, pharmaceutical marketing should be limited to presenting facts and should be targeted only to populations that actually need pharmaceutical treatment (which was certainly not the case in the marketing of menstruation suppressants and erectile dysfunction medications), without forgetting non-pharmaceutical alternatives (possibly low-tech, such as action on lifestyle changes or psycho-social therapies). Marketing should not rule out choices that are potentially most conducive to responding to consumer needs. Shaping consumers' desires for the financial interests of a company may therefore be seen as wrongful since it negatively affects consumers' perceived available choices, thereby limiting their autonomy to make informed choices. The nature of DTCC is that people are exposed to it without choosing and this can have an impact in shaping how they process information, their decision-making contexts, their social expectations, etc. From a deontological perspective, DTCC arguably does not empower individuals, as defended by its proponents, but rather frames the perception of available choices for commercial ends.

Companies using DTCC may argue that, as for any other company, they are entailed to reach out to their consumers and that their duty is limited in disseminating selected but not false information about their products. However, the fact that marketing a product affects human health, as do drugs, entails a duty proportional to the potency of the product. The duty of marketing, then, is to ensure the dissemination of quality, unbiased information, and to act

benevolently towards consumers by insuring their empowerment and fostering their capacity to choose between salient options. To meet the requirements of dutiful practice, it is therefore important to consider whether a contemplated practice may contradict pharmaceutical marketing moral obligations that are to educate, inform and empower consumers. The question must be whether a contemplated practice may frame consumers' understanding and choices, and so capacity to make informed choices and thus disempower consumers. If this is the case, then the practice does not respect dutifulness.

Virtue Ethics

What are the moral virtues on which marketing practices are to be evaluated? Some might argue that is should be the core reason of existence for marketing: persuasive influence (Palmer, 2017). However, this is a strategic and *a fortiori* an amoral virtue. Solomon (1992) argues that an amoral activity, having as objective only profit maximization, cannot be the grounds on which to found a virtue ethics approach to business practices. This does not undermine the value of virtue ethics in business, but implies that morality cannot *only* be grounded on the commercial purpose of marketing. According to Palmer (2017, p. 1027), "The focus on character, integrity, and community in virtue ethics offers a more robust, normative, and practical foundation for ethics in marketing than either deontological or consequential theories alone can provide." While the virtues of interest vary according to different authors – e.g., honesty and integrity according to Zakhem (2017), fairness and respect according to Coleman (2017) – it is possible to evaluate business practices based on virtues of the company (e.g., in mission statements) and its employees.

Foundational ethical virtues in pharmaceutical marketing must be different than those for other business practices (e.g., those that not subject to regulatory scrutiny to protect the health of individuals). From a classic free-market standpoint (such as that of Adam Smith), personal benevolence plays no part; only justice has a role in policing the antagonism stemming from mutual self-interest (Coleman, 2017). In the case of pharmaceutical marketing, however, marketers' benevolence is required, i.e., fostering the betterment of consumers' informed decisions. If this is not the case, then marketing loses its moral legitimacy. The virtues to be put forward would be honesty (truthful information conveyed), integrity (diligent practice), respect

(respect of consumers, their needs and their privacy). By ensuring the preservation and expression of these virtues in their campaigns, pharmaceutical marketers would ensure a conformity of their act with what is virtuously expected of them.

Virtue ethics involves examining moral decisions based on the agent's character. However, this is much more complicated than assessing consequences or determining whether an agent has duly acted upon a duty. Pharmaceutical companies increasingly present themselves as champions of patient empowerment and of integrity. Some notable examples include the following: "We are thus committed to promoting our products responsibly [and we] believe that it is important to educate patients" (Pfizer, 2017b); "The new solutions – including online communities, apps and information portals – all aim to empower people with skin conditions to manage their disease." (LEO Pharma, 2017, p. 7); "We will maintain integrity in everything we do by working to consistent global standards of ethical sales and marketing practices in all our markets" (AstraZeneca, 2017, p. 44).

Yet, there is no lack of examples pointing to the contrary. For instance, cases 1 and 2 (menstrual suppressor and erectile dysfunction) presented above involved campaigns that deployed a rhetoric emphasizing the medicalization of everyday problems (with a dubious self-assessment quiz) and which engaged in disease-mongering (extend the definition of an at-risk population). Making use of the popular context or of a persuasive device – such as a misleading quiz or the use of a popular spokesperson to generate more favorable attitude towards DTCC (Bhutada et Rollins, 2015) – to increase the effectiveness and persuasiveness of their promotional messages are good examples where the industry has adopted an attitude contrary to a virtuous behaviour towards consumers. Instead, such DTCC aims at expanding markets and creating new populations as targets for treatments, thus fostering the amoral commercial virtue. From a virtuous standpoint, such attitudes are at best morally questionable, if not unethical.

Some marketing strategies go so far as to establish a personality for each of their brands in order to humanize a product and associate it with a set of traits, and thus better consolidate the image of a product in the minds of consumers (Katsanis, 2016). Dependable, innovative, original, practical, reliable, responsible, stable, solution-oriented, successful and unique are all traits that

marketers may use so that brand personality "enhances marketing effectiveness, allows an emotional connection with the brand, and may influence the choice of a particular brand" (Katsanis, 2016, p. 67). It is a wonder whether marketers, while designing their campaign, exhibit the same traits as they are suggesting are part of their products. A virtuous marketing behaviour would be to faithfully associate traits to products based on a faithful posture of the marketers.

Another important consideration lies in the repetition of virtuous conduct, to reinforce moral conduct and the persistence in time of virtuous traits. This also represents a point where industry practices are at odds with expectations of a virtuous person, because the cases of misconduct (illegitimate and illegal) continue to repeat themselves. One has only to think of all the cases where the companies were reprimanded by regulatory agencies, and often forced to pay heavy fines and to offer their customers substantial compensation, for having conducted massive DTCA campaigns in jurisdictions where such practices are prohibited (Weintraub, 2017).[34] It is therefore important to anchor the virtues in the daily practice of marketers, as this is more likely to consolidate and ensure the persistence of moral practices: and in line with broader arguments in business ethics, virtuous practice can be a guarantee of commercial efficiency and greater stakeholder satisfaction.

One of the limitations of deontological rules to follow and of morality based on an analysis of the consequences of actions is that these may neglect the context in which a decision is made, and the posture of both the individual and the organization in which they work. Adding to this, virtue as one of the bases of morality thus justifies the integration of codes and decisions within a strong virtuous corporate culture that is grateful for and recognizes its positive role in society (Robin et al., 1989; Williams et Murphy, 1990). This does not mean that marketers must be

[34] There have as yet been no big scandals about social media, or in-person DTCC. In the former case, the FDA is still considering how to regulate social media communications (Food and Drug Administration, 2016). One of the only documented case relates to a warning letter sent by the FDA to the company Duchesnay in 2015 about a sponsored message that their spokesperson Kim Kardashian sent to her millions of followers on Instagram, about the drug Diclegis (to treat morning sickness) and which did not mention the side effects of the product (FDA, 2015b). No regulatory attention has been yet been given to in-person interactions between pharmaceutical representatives and consumers (Bélisle-Pipon, 2017). Thus, for these two types of DTCC, there is as yet no surveillance or sanctions, in comparison with the oversight given to television, radio, or web-based communications.

totally altruistic, which would mean that profitability does not matter to them (Ramanathan et Swain, 2017). A fair balance can, however, be found among the virtuous marketer who is "moderately altruistic" and who is therefore ready to sacrifice some sales gain for the sake of adding value for consumers. In so doing, it can be possible to have a profit-oriented practice while seeking to maximize the value of communication that is also beneficial for the consumer. This may require courage, according to Williams and Murphy (1990, p. 19), on the part of marketers "to act to protect human welfare even in the face of incomplete information and in the integrity and humility displayed in communicating with consumers about possible difficulties with a product". The virtuous marketer will therefore be able to be courageous and behave with integrity and benevolence towards consumers whilst conducting marketing activities that also favour the interests of their employer.

The virtuous agent is one who succeeds in adopting a genuine and benevolent posture while assuming the role for which they are paid. However, contrary to Hoppe (2017, p. 419), who conceives the evaluation of a virtuous business agent simply as a calculation of the profits generated – "The capitalist's profit indicates that he has successfully transformed socially less highly valued and appraised means of action into socially more highly valued and appraised ones and thus increased and enhanced social welfare" – it is expected that the agent does not simply adopt a posture intended to increase the desirability of a product in the eyes of consumers. This posture must also take into consideration the consumer, what he or she seeks without creating needs or biasing them. Along these lines, there have been calls by health regulators for a more virtuous posture, notably by Former FDA commissioner Robert Califf, who challenged pharmaceutical marketers: "Your efforts should be truthful and non-misleading. Truthful you get, non-misleading is really hard. It's like a bad marriage, it's not what you say. It's what you didn't say. The misleading part is where you need to focus." (McCaffrey, 2017b) It is thus important for marketers to be interested in their own motivations and general posture towards consumers and society. So, before performing a certain practice, they may ask themselves if their intent is harmful or benevolent towards consumers and other societal stakeholders? Such an inquiry will help agents appreciate whether their behaviours are virtuous.

Social Contract

Contractual ethics emphasizes the recognition, by self-interested agents, in the value of designing and obeying regulations that constrain behaviour for mutual benefit. According to Dunfee and colleagues (1999, p. 14), as a compelling normative moral foundation for marketing, "social contract theory appears promising because of its clear correspondence to the exchange relationships central to marketing thought and practice." In this exchange relationship, each actor has to gain something that would not have been possible if there had been no interaction. To better understand the implications – as well as the correlate social responsibilities – of such a relationship, it is helpful to imagine what would happen if an actor (or a type of practice) is withdrawn from the current state of affairs, and to evaluate whether the situation of stakeholders is worse, not changed or improved.

In the specific case of pharmaceutical marketing, the test would involve imagining what would change if pharmaceutical marketing as a whole, or certain of its practices, did not take place. Such a test establishes what an actor or practice actually brings to the other parties, e.g., what pharmaceutical industry offers, in terms of information and empowerment, to consumers and society. In the context of direct communication to patients, from the point of view of self-interested agents, it is essential that these practices are to the advantage of all parties; commercial practices will need to meet a number of conditions to ensure that communications are not only about profits but also about information and consumer empowerment. If consumers and society are better off without certain DTCC practices, then this entails that these marketing practices are not morally salient and do not respect the social contract, because they are not mutually beneficial. Applying this test to the campaigns for erectile dysfunction and menstruation suppression, it is possible to conclude that both have a questionable contribution to information and the empowerment of consumers. In addition to not being essential for consumers, each case raises its share of issues with regards to biased and misleading information, and thus the mutual benefit for both industry and consumers is far from obvious.

In addition to being mutually beneficial, agents must be able to police themselves and each other on the basis of the agreed upon terms of the social contract (for DTCC, informational quality

and fostering empowerment), and practices must be justifiable, to be moral. Consequently, a practice that contravened the terms of the social contract would be judged unjustifiable and morally reprehensible.

Increasingly interactive and digital forms of DTCC thus pose multiple challenges from the perspectives of a social contract. The abundance, low cost and private nature of these communications make the policing DTCC practices particularly difficult, in comparison to classical forms of marketing using broadcast media (e.g., TV, radio) for which a pre-clearance might be required and possible, depending of the jurisdiction. But for social media DTCC, even if a certain practice may be deemed reprehensible, their eminently direct aspect makes them almost impossible to monitor. Aside from the social media company (for whom this kind of communications may represent important revenues) and the consumers who receive these messages, it is very difficult for a third-party (e.g., health regulators) to access and evaluate the nature and content of these communications. The same is true for invitations and for the content conveyed during in-person events, for which there is no systematic way to monitor content; up to now, regulators have had to rely on the very few published consumer experiences. This situation means that, at a minimum, companies engaged in such DTCC must self-regulate because they are only ones with control of all the means – knowledge about and the quality of the information conveyed – used to reach consumers. There is thus a major flaw in the social contract, because other actors (consumers, regulators) do not have the means to efficiently police industry behaviour.

The pervasiveness of DTCC and its ability to easily permeate consumers' private spheres is particularly morally problematic. It creates important moral challenges for societies, because people need to have access to drugs, but they may not need to receive pharmaceutical DTCC. Actors attempting to resolve these challenges – whether they be regulators, industry, patient interest groups, for example –will inevitably need to assess their own stance on the matter, and consider what they can do themselves to empower patients as consumers in their choices about drugs (and other options) to address their healthcare needs. This may often be very modest, and their role limited to establishing the rules of the game that companies must comply with in order to reach consumers.

Why is such social contract relevant and is there anything specific with about a pharmaceutical marketing social contract? A complex agreement governs and regulates the practices involving drugs. This includes the temporary exclusivity of exploitation of a product granted by the complex patent system (which is the foundation of the pharmaceutical industry's business model), drug approval, negotiation of prices with public and private insurers, and drug promotion. Within this complex agreement, the terms are (ideally) negotiated to be mutually beneficial for industry and for the society (state) in which it operates (taken in the broad sense, including government, institutions, citizens, economic market). The agreement, even if it is intended to be beneficial to all, is subject to influences and dynamics of power which raise the risk that the contract is unbalanced and only profitable for some. Corporate practices have a role in the production of health and disease, and may even according to Freudenberg and Galea (2008), be thought of as social determinants of health that shape health and behaviours. What makes the pharmaceutical marketing social contract particular is the potency and health-related impacts of drugs, and this leads to further moral requirements that go beyond what would be required of other commercial r sectors. The terms of the pharmaceutical social agreement pertaining to marketing require practices to be informational, educational and empowering, and are related to what consumers need and expect from the industry.

As promotional practices can be deemed as socially irresponsible (D. Harker, 1998), and companies are aware that they need to change their practices for better social acceptability, "social expectations are rapidly changing, and educational and promotional practices that have been widely used by the industry must be re-evaluated" (Novartis, 2017, p. 69). As the pharmaceutical sector recognizes the need to go beyond the law and compliance, "Our strict internal standards, going beyond compliance with the law, have been developed to ensure that the information we share with patients is scientifically sound, balanced, easy to understand and helpful in encouraging them to consult with a health care professional" (Pfizer, 2017a, p. 36). A contractual approach would therefore argue for marketers to recognize the terms of the tacit agreement allowing them to reach out to consumers, and so make sure that their practices are based on mutual interest, respect, integrity and reasonableness, as well as to comply with guidelines fostering conformity with accepted principles of right and wrong in pharmaceutical

marketing ethics. Marketers should make sure that their practices are always justifiable to themselves and to others and that they are fulfilling their part of the social contract.

Synthesis: Implications for accountable DTCC practices

Patients as consumers of health products, such as pharmaceutical drugs, should be provided with balanced and credible information so that they can make informed decisions about how best to manage their health. The messaging must also not make use of or resonate with certain contexts to woo consumers into thinking that they are in need of a certain product when they have no medical reasons. This view is recognized by the four theories previously discussed (i.e., consequentialism, deontology, virtue ethics, social contract), and which are frequently referred to in the business ethics literature (and applied ethics more generally). Each can contribute to helping to understand the complex situation that is contemporary DTCC: according to the duty to respect the autonomy of individuals, the population consequences of misinformation and over-medicalization, the posture expected by a virtuous person, and also by the terms of the social agreement that stipulates that marketing is justified on the basis of the sharing of benefits (for individuals as well as for the company). The moral "bottom line" is that DTCC must be informative and empowering, notwithstanding the differences in the various moral theories that could be applied. This view may sound tautological, because it is already what is invoked by both proponents and opponent of DTCC. However, they do not agree on the moral (and social) implications of DTCC practice, nor on the impact of the social context on how DTCC are conveyed to consumers. The analysis of the four theories allows one to define the morality of pharmaceutical marketing and to detail what is expected of agents who work in DTCC.

Pharmaceutical marketing practices highlight the evident conflicting imperatives that are 1) the moral expectation for information and empowerment and 2) the commercial expectation that marketing must drive drug sales, which serves as a benchmark to evaluate the practice of marketers. Does this conflict of imperatives mean that pharmaceutical representatives and companies are not the best suited to directly support patients in their decision-making? Most probably. There are good reasons to believe that these two positions are morally incommensurable. And pragmatically, aligning current practices and regulations with these moral expectations is likely impossible, especially in countries that have a lax attitude towards

advertising of medicines. In the last few years in the United States, prohibitions on commercial speech have been undermined by various courts of law; this has been particularly evident with regards to off-label promotion, where there have been flagrant examples of DTCC that delivers information that is not medically appropriate nor in compliance with regulatory requirements (Kapczynski, 2016; Robertson et Kesselheim, 2016). Although the United States has a particularly liberal attitude towards free commercial speech (compared to other jurisdictions) (Ghinea, Lipworth et Kerridge, 2015; Kapczynski, 2016), it would appear easier to work towards a change in business practices through self-regulation than by legislative change. This is even more important considering that a majority of communicational efforts via social media and the Internet come from the United States; given their cross-border nature, such DTCC can reach virtually any consumer regardless of their geographical location, so it is probably more reasonable and pragmatic to use a harm reduction approach, e.g., through self-regulation practices. That being said, the fact remains that this type of practice continues to take place and, except if they are prohibited, it is advisable to support employees regardless of their jurisdictional context.

The analysis of the ethical dimensions of DTCC made it possible to pinpoint the main tensions and issues with which to set the table for a framework of practices and behaviours to foster and to proscribe acceptable marketing practices. This is all the more important, since "Absence of a clear consensus about what is ethical conduct for marketing managers may lead to deleterious results for a business." (Ferrell et Gresham, 1985, p. 87) It is therefore essential to equip marketers with clear ethical benchmarks anchored in an agreement on ethical terms for an appropriate and moral practice of pharmaceutical marketing, so that their practices can be mutually beneficial for all. A code of ethics is the usual way of formalizing ethical behaviour in professional practice (and embedding it in the ethics of the professional association), and can greatly assist in the implementation and monitoring of practices. But as a first step towards enunciating ethical guidelines for supporting marketing professionals, we instead propose an ethical oath that sets out the main lines for the ethical and social commitments of pharmaceutical marketers.

Self-regulation: an oath for pharmaceutical marketing professionals

Obviously, pharmaceutical marketers are not professional who have, like clinicians with their patients, an overarching imperative to act in consumers' best interests. This is no formal fiduciary (trust) relationship binding marketers to the targets of their professional activities. However, marketers can and do have a major impact on the lives of individuals regarding how health-related decision-making is shaped (Katsanis, 2016). *A fortiori*, as for DTCC's legitimacy, the legitimacy of marketers' practices derives from its moral and social acceptability, so it is important that their practice reflects what is expected of them and then can legitimately continue to communicate with consumers.

The most famous oath is that of Hippocrates, which has inspired the codes of ethics of most health professions (updated to modern practices and norms, and also dropping references to ancient Greece and its gods). In medicine, each graduating physician must take an oath and swear that their practice will be fair and ethical (Hulkower, 2016). Other professions that do not have such clear fiduciary duties towards others, have developed oaths for their members as a means to recognize the scope of their professional actions and as a means of articulating broad moral guidelines. For example, academics in the United Kingdom have ethical standards to maintain their "social licence to operate as scientists" and to foster the trust relationship with society (Cressey, 2007). Another example involves data scientists who realized, following the financial crisis in 2008, that they could have an important (even unforeseen) impact on the life of individuals, so some began to reflect on the self-regulation of their practices and developed an oath to steer their profession in a way that will foster positive social outcomes (O'Neil, 2016). So, on the basis of the ethical frameworks and cases discussed, and with the inspiration of various professional oaths, we propose an oath for pharmaceutical marketers that marketing professionals and their associations could adopt.

I swear to fulfill, to the best of my ability and judgment, this covenant:

1. *I will respect the hard-won scientific gains and knowledge on which pharmaceutical drugs have been developed and for which they have been approved.*
2. *I will make sure that the presentation, interpretation and review of scientific evidence is honest and accurate. I will ensure that any information that is provided or used in*

pharmaceutically sponsored communication or events is unbiased and does not knowingly mislead, or allow others to be misled.

3. *I will remember that pharmaceutical communications to consumers is legitimized on the grounds that it provides useful and unbiased information on which consumers may make informed decisions about whether or not to take a certain treatment. I will not frame the communications so that consumers are inclined to consider as being true claims those that are not relevant and/or beneficial for them.*
4. *I will not unduly emphasize or over-represent a product's benefits, and will make sure that the risks and adverse events are presented in a complete, understandable and accessible way so that consumers are more informed about the product and empowered in their decision making.*
5. *I will avoid fostering the medicalization of health or encouraging disease-mongering, and refrain from trying to convince essentially well people that they are sick, or slightly sick people that they are very ill. I will refrain from presenting a product as prevention when it instead fosters disease-mongering.*
6. *I recognize that I have dual obligations: first towards my employers and to those who contracted me for a task, to help them make their product(s) profitable; and second, towards consumers for whom I need to ensure that pharmaceutical marketing only fosters the 6 rights to medication (right patient, right medication, right reason, right dose, right route, right time).*
7. *I will be careful with the marketing of lifestyle and life-threatening medications, providing only relevant and scientifically proven facts, and will not take advantage of a context or situation that is unfairly conducive to the sale of a product.*
8. *I will make sure not to exclude alternatives to medications that may be more salient for some consumers, nor to present them in a manner which appears to be less advantageous than a pharmaceutical solution.*
9. *I will respect consumer privacy and will not seek or collect information that is sensitive. I will try to minimize the intrusion into the privacy of consumers, and avoid co-opting relatives to change perceptions about a product or condition.*

10. *I will ensure that pharmaceutical communications (directly or indirectly) sponsored by companies are clearly identified as such and will not be perceived as a public health campaign, independent of the industry.*
11. *I will make sure that whenever I involve healthcare professionals or invite any person to communicate with consumers, that their conflicts of interest are declared. I will never encourage or participate in corrupt practices and professional misconduct.*
12. *I will remember that drugs represent significant costs to patients as well as to society, and that their purchase may affect the person's family and economic stability as well as generating undue collective costs.*
13. *I will remember that I remain a member of society, with a power of persuasion that can cause serious consequences if not used and deployed for the benefit of patients and society.*
14. *If I do not violate this oath, may I enjoy trustworthiness and be recognized as a reliable source of information that is integral to improving health and social well-being.*

In stressing the moral consequences of the actions of marketing professionals, such an oath would advance ethical and critical thinking and could help increase public support (and even trust) for corporate-driven information communications about pharmaceutical drugs.

Conclusion

Pharmaceutical marketing involves a set of practices with a putatively benevolent character – i.e., seeking to inform and educate consumers about treatments they may need – but whose primary objective is to make products profitable. A vast array of means of DTCC are now available to pharmaceutical marketers to reach an ever-increasing number of consumers with messages related to drug promotion. But the ethics of DTCC practice does not stop where government regulation ends and not all practices are equally ethical when compared with the moral arguments used to justify its acceptability, i.e., the provision of meaningful and efficient consumer information, that promotes education and empowers consumers to make informed and autonomous choices. Hence, one of DTCC's key dimensions is how the message can resonate with a social context and mislead consumers. Socially responsible and ethical decision-making

must therefore be based on the integrity of the messaging (legitimate content and avoidance of manipulative rhetoric), the social contexts as well as the particularities of products and consumers' needs and hopes. It is in this "messiness" that ethical reasoning takes on its full meaning and that employees can be recognized as having an important role to play in (self-)regulating their practices.

Despite the lack of consensus about the moral foundations of a marketing ethics (e.g., consequentialist, deontological, virtue ethics, or social contract) or the ethical frameworks that should guide pharmaceutical marketers, it is nonetheless possible to analyse the ethics of marketing practice from different theoretical perspectives and so draw conclusions about acceptable and unacceptable behaviour. It is also possible to establish clear and universal guidelines, such as in the form of an oath, to pave the way for the codification of ethical principles that can help marketing professionals better align their practice with credible ethical standards. Companies have an interest in promoting "legally and ethically impeccable conduct by all employees in their daily work, because the way they carry out their duties affects company's reputation" (Bayer, 2017, p. 184). It is thus essential to support and equip pharmaceutical marketers with ethical standards for their day-to-day practice, that enable them to conduct business operations in line with the ethical expectations for pharmaceutical companies, and in so doing, help regain public support (and even trust) for corporate-driven information communications about pharmaceutical drugs.

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Des repères éthiques dégagés à une bioéthique pharmaceutique pertinente au marketing pharmaceutique

Le chapitre précédent a permis d'établir les fondements éthiques sur lesquels doivent être apprécier les pratiques de CDCM. À travers les grandes théories morales, il a été possible d'établir ce qui était moralement attendu en termes des implications des CDCM (conséquentialisme), des devoirs des entreprises et de ses employés (déontologisme), de l'intentionnalité derrière ces communications (éthique de la vertu) et de ce qui socialement justifie la pratique (contrat social). L'objectif étant de soutenir et d'équiper les spécialistes du marketing pharmaceutique avec des normes éthiques pour leur pratique quotidienne pour qu'ils soient à même de mener des opérations commerciales conformes aux attentes éthiques. Conséquemment, ces dimensions éthiques ont été résumé sous le format plus accessible de 14 impératifs constituant un engagement éthique. Il a été postulé que la conformité des employés à l'engagement éthique permettrait de contribuer à accroître le soutien public (et même la confiance) envers les CDCM.

La forme de l'engagement, tel que postulé, est un serment que les marketeurs promettraient solennellement de suivre. Modélisé sur la base des versions modernes du serment d'Hippocrate, il en appelle au professionnalisme des marketeurs de prendre en compte leur impact social et éthique. L'engagement leur demande de souscrire à des pratiques qui soient en double adéquation avec les demandes de leurs employeurs de faire connaître leurs produits et contribuer à leur vente ainsi qu'aux attentes pro-sociales pour que cela n'ait pas de conséquences indésirables sur les patients et la société. D'abord et avant tout, l'engagement est un dispositif visant à susciter la réflexion à propos des repères éthiques qui doivent guider les pratiques du marketing pharmaceutique, ainsi que d'entamer une discussion quant aux moyens d'outiller les employés et guider la prise de décision. Cela étant, il est possible de penser concrétiser la mise en application de l'engagement, en vue de 1) son établissement comme un code de conduite au sein de l'industrie, et 2) voire même comme précurseur à la structuration des marketeurs

pharmaceutiques comme professionnels, ce qui formaliseraient les repères éthiques en une déontologie à suivre.[35]

Les engagements éthiques, les serments, les codes d'éthique et les lignes directrices en matière d'éthique mis en place par une compagnie ne sont pas en soi une panacée puisque: « [they] are not strong enough to alter employees' ethical decision making behavior, but combined with other tools can help make employees more cognizant of their own personal ethical influence on the organization » (Cleek et Leonard, 1998, p. 628). Ainsi, l'une des façons les plus efficaces d'agir sur les comportements éthiques des employés est de créer un environnement fertile au respect des attentes légitimes des consommateurs. Cela passe par de nouvelles structures comme un comité ou un programme d'éthique, la formation des employés et la conformité des décisions des dirigeants avec les valeurs et principes éthiques revendiqués (Ferrell et Gardiner, 1991). L'objectif est donc de donner un contexte à l'éthique en entreprise, de laisser une marge de manœuvre aux employés pour la réflexion et l'évaluation de leur pratique, ainsi que des ressources pour guider les employés à adopter des comportements et des réflexes éthiques.

C'est *in fine* ce que cherche à faire le prochain chapitre en postulant que la bioéthique pharmaceutique puisse influer sur les pratiques et la prise de décision en entreprise pour favoriser l'adoption de comportements éthiques et soutenir le solutionner le dilemme. À elle seule, elle ne saura résoudre l'ensemble des enjeux éthiques découlant des pratiques de marketing. Quoiqu'elle puisse, à tout le moins, soutenir la prise en compte des impératifs

[35] Bien que l'objet de cette thèse ne soit pas de proposer la professionnalisation des marketeurs pharmaceutiques, cela mériterait tout de même une certaine réflexion. Les marketeurs ne forment pas une profession régulée comme les médecins, infirmières, pharmaciens et autres professionnels de la santé. Cela étant, considérant qu'il y a un besoin de reconnaissance de leur rôle clé dans les enjeux liés aux CDCM, mais également de la nécessité de mieux baliser leurs pratiques, ne serait-il pas envisageable de les reconnaître comme professionnels à part entière? Cela justifierait d'autant plus de les autonomiser et les responsabiliser à mener de meilleures pratiques, mais également offrirait une structure pour leur formation, la mise à jour de leurs compétences – notamment éthiques – et pour baliser et policer leurs pratiques. Le présent serment pourrait servir de jalon à la fois pour orienter le balisage des pratiques en marketing, mais également contribuer à la structuration de mécanismes contraignants permettant de surveiller et d'agir sur les pratiques de ses membres. Bien que cette proposition mérite d'être approfondie, elle n'est pas nécessaire pour la mise en place de repères au sein de l'industrie. D'autres avenues existent dont la formalisation d'une structure, au sein de chacune des compagnies, soutenant la prise de décisions et les comportements éthiques comme il sera vu au prochain chapitre. Cette avenue s'inscrit ainsi avec l'objectif de la thèse, de proposer un cadre pour guider les employés dans leur pratique quotidienne et les soutenir à l'interne lorsqu'ils font face à des enjeux éthiques.

éthiques et pro-sociaux spécifiques au marketing et de viser à trouver un équilibre avec les pratiques promotionnelles, qui demeurent cruciales pour la compétitivité et la rentabilité d'une compagnie (Snyder Bulik, 2016). Ainsi, sur la base du chapitre précédent, le chapitre suivant poursuit la réflexion et les modalités pour outiller les employés de l'industrie à concilier les dimensions commerciales et sociétales. L'article « *Pharmaceutical Marketing Ethics: Bioethics Frameworks as a Guide for Ethical Decision-Making of Industry Employees* », soumis au *Journal of Bioethical Inquiry*, s'intéresse aux premiers efforts d'énonciation et de systématisation d'une bioéthique pharmaceutique.

L'article analyse ces propositions, soit deux cadres de bioéthique pharmaceutique présentés dans le Chapitre 2 – et ayant comme fondement une approche par principes inspirée de Beauchamp et Childress (2013) – ainsi que l'engagement éthique présentée précédemment. Puis, est proposé une intégration des repères éthiques portant sur le marketing pharmaceutique du dernier chapitre en élargissant la portée de ces deux cadres de bioéthiques pharmaceutique, qui ne portent que sur les activités de R-D. Il est invoqué que l'inclusion des considérations commerciales sous la forme d'une double orientation des principes classiques en bioéthique pourrait servir à résoudre bon nombre d'enjeux qui sont actuellement hors du ressort de la bioéthique, la rendant même pertinente à une intégration au sein des entreprises. Le développement et le déploiement de cadres éthiques à utiliser par l'industrie pharmaceutique représente une avenue pour guider les réflexions des divers acteurs au sein du secteur pharmaceutique en ce qui a trait aux attentes sociales et éthiques concernant les pratiques de marketing. Une bioéthique pharmaceutique effectuée au sein des entreprises saurait permettre de soutenir les spécialistes du marketing pharmaceutique dans leur pratique par des repères éthiques clairs, acceptés par toutes les parties prenantes, pour guider leur pratique professionnelle et assurer que les pratiques de marketing pharmaceutique et de CDCM soient à l'avantage mutuel tant de l'industrie que de la société.

Chapitre 7. L'éthique du marketing pharmaceutique comme guide pour les employés de l'industrie

Pharmaceutical Marketing Ethics: Bioethics Frameworks as a Guide for Ethical Decision-Making of Industry Employees

Bélisle-Pipon, J.-C. "Pharmaceutical Marketing Ethics: Bioethics Frameworks as a Guide for Ethical Decision-Making of Industry Employees". Soumis au *Journal of Bioethical Inquiry*.

J'ai écrit l'article. Bryn Williams-Jones a eu l'amabilité de faire une révision linguistique et a commenté sur l'argumentaire de l'article.

Abstract

Pharmaceutical marketing is often regarded as vector for conveying biased information to increase the sales of medications, and so associated with calls for the industry to better self-regulate its practices. This, of course, raises questions about the appropriate management and resolution of marketing-related ethical issues, and has thus been the subject of much attention and critique from bioethics scholars. However, relatively little effort had been given to conceptualizing or defining frameworks for ethical pharmaceutical marketing practices, that can help pharmaceutical professionals understand and resolve the ethical issues that they encounter in the industry, particularly related to clinical and research concerns. Three notable exceptions are an ethics oath for pharmaceutical marketers, and two pharmaceutical bioethics frameworks founded on a principle-based approaches to ethical decision-making. Following a presentation and analysis of the three proposal frameworks, I propose a means to broaden their scope and applicability beyond R&D activities to the considerations related to drug promotion. The development of ethical frameworks for use by the pharmaceutical industry is a promising avenue for companies seeking to meet with the social and ethical expectations regarding marketing practices. Pharmaceutical marketers need clear ethical benchmarks, agreed to by all stakeholders, to guide their professional practice and ensure the mutual benefit for both industry and society of pharmaceutical marketing.

Keywords: pharmaceutical; marketing; ethics; frameworks; professional; ethical guidance

Introduction

In Western countries, it is widely accepted that patients should be provided with balanced and credible information so that they can make informed decisions about how best to manage their health. But sources are not always reliable and finding information that is balanced, unbiased, and understandable may be particularly challenging for patients who may lack the necessary medical and scientific literacy (Kaphingst, Rudd, DeJong et Daltroy, 2005; Sullivan et Campbell, 2015). With its wealth of experience in marketing and significant financial resources that far surpass those of national health regulators, the pharmaceutical industry has become one of the principal actors in communicating information to patients – as consumers of medications – in a manner that is accessible and understandable (Katsanis, 2016). However, direct-to-consumer communication (DTCC) practices by pharmaceutical companies have been widely and systematically criticized for their problematic informational value (Mulinari, 2016b), for the fact that they create unnecessary demands by patients (Frosch et al., 2007), and contribute to an over medicalization of the population (Mintzes, 2002; Mintzes et al., 2009).

DTCC practices, in general, have two conflicting imperatives (Mackenzie et al., 2007; Velo et Moretti, 2008): 1) the social expectation for information and empowerment, and 2) the commercial expectation that marketing must drive drug sales, which is a benchmark to evaluate the practice of marketers (Bélisle-Pipon et Williams-Jones, s.d.). Both imperatives are used, simultaneously, to justify pharmaceutical practices, but each for different stakeholders: the former for regulators and patient advocates, and the latter for industry stakeholders and shareholders (Bélisle-Pipon, 2013). Without these two imperatives, the promotion of medicines would simply not take place. The pharmaceutical industry would not invest time and energy if there were no financial gains, and the drug marketing practices would not have social and regulatory legitimacy if they did not possess informational qualities. Obviously, the social value accorded to DTCC varies greatly between jurisdictions (Bélisle-Pipon et Williams-Jones, 2015b). Two OECD countries – the United States and New Zealand – have taken permissive approaches to DTCC regulation by permitting DTC advertising (DTCA), and so they are more prone to attribute informational quality to DTCC. Most of the other OECD countries have taken a prohibitive approach, banning or severely limiting DTCA and only permitting DTC

information (DTCI) in the form of disease awareness, help-seeking and other non-drug related communications.

Although they coexist, the two imperatives of informational quality and marketing-driven sales are often difficult to reconcile. In part, this is the result of (unreasonable) expectations by the financial markets (i.e., investors) for continued high drug company profit margins, which then leads to very high targets for and pressure on pharmaceutical marketers (Katsanis, 2016). It should not be surprising, then, that "marketing activities present some of the most discussed and challenging ethical issues in the contemporary world of business" (Palmer, 2017, p. 1028), or that these considerations receiving more frequent attention in the bioethics literature (Bélisle-Pipon et Williams-Jones, s.d.).

Despite more than half a century of existence as a field of study and professional practice, and having provided countless analyses of the ethical issues associated with the pharmaceutical industry, bioethics has yet to provide a convincing response to one of the most challenging questions in this sector: how to empower those within the industry to recognize and resolve ethical dilemmas and to act ethically (Brody, 2012; Philpott et Baker, 2010). Although there is abundant literature in business ethics about corporate social responsibility specific to the pharmaceutical industry (Acquier, Daudigeos et Valiorgue, 2011; Fort, 2014; Leisinger, 2005; West, 2012), as well as an extensive critical bioethics literature about the (often negative) interactions between the pharmaceutical industry and public actors (e.g., regulators, physicians, patients) (Bélisle-Pipon, 2013; Brody, 2012), there has been very little work on actual concrete mechanisms for understanding and conceptualizing the vast array of issues that surround the pharmaceutical industry or how to "do bioethics" within companies (Brian, 2012). Pharmaceutical industry decision-makers and employees do not have good practical bioethics tools (e.g., ethics frameworks, decision making guides) to cope with and manage the issues that arise in practice (Brian, 2012; Magnus, 2002); and this is particularly problematic because there is an "absence of a clear consensus about what is ethical conduct for marketing managers [and this] may lead to deleterious results for a business" (Ferrell and Gresham, 1985: 87). A possible solution, however, may lie in bridging the gap between the two solitudes of bioethics, on the

one hand, with its often very critical gaze of industry, and business ethics on the other, with its attention to industry interests and corporate social responsibility.

I argue that bioethics can help shed light upon important ethical challenges facing industry, and even accompany the industry in this transformation, but this requires moving bioethics beyond its current idiosyncratic limitations and tendency to neglect (bio)ethics developed within and used by companies. First, bioethics must be understood more broadly than its traditional narrow focus on issues in clinical ethics and research ethics (Wolpe, 2000), and so also include components such as organizational ethics, public health ethics, etc. In this broader perspective, bioethics would then also include pharmaceutical (bio)ethics[36], as I suggest, a natural extension of bioethics as the field has long been interested in pharmaceutical industry practices, even if mainly through denouncing industry influence on actors in the health sector. This latter critique is usually presented as a confrontation of "society vs industry" (Bélisle-Pipon, 2013), with some scholars even questioning whether a corporate pharmaceutical ethics can exist (Rich et Ashby, 2015). But while such criticisms have sought, quite rightly, to name the many problems with corporate behaviour, they often take the form of blaming the industry but provide little in the way of constructive recommendations to guide decision-making processes. To be relevant and foster genuine changes in the industry, bioethics scholars must also recognize that commercial imperatives are legitimately at the very heart of the pharmaceutical industry; and so any proposed solutions must take this dimension into account, if they are to avoid being labeled as naive and irrelevant (LaMattina, 2013).

A recent example of this more open or broader bioethics approach is an oath for pharmaceutical marketers that I proposed (Bélisle-Pipon et Williams-Jones, s.d.). Following a critique of DTCC practices, they present a model oath that could be one tool to guide the daily conduct of pharmaceutical marketers and provide content for the establishment of marketing-related pharmaceutical ethics guidance, such as theoretical and operational frameworks. In other recent papers, two groups – American pharmaceutical industry employees, Van Campen and colleagues (Van Campen, Allen, et al., 2015; Van Campen, Therasse, Klopfenstein et Levine,

[36] The terms "pharmaceutical bioethics" or "pharmaceutical ethics" can be used interchangeably.

2015b, 2015a), and Australian academics Lipworth and Little (2014) – have developed principle-based pharmaceutical bioethics frameworks for industry employees to conduct bioethics analyses in the contexts of research and development (R&D) and medical affairs.

These three propositions pave the way for a specialised bioethics scholarship – pharmaceutical bioethics – that aims to work with and within the industry, that is, where important decision-making processes take place and which have led to major ethical challenges (e.g., misleading advertisements, diseases-mongering, creation of demand for pharmaceutical solutions). In developing ethical guidance for industry marketing activities, as well as to providing grounds for a more comprehensive ethics framework for all pharmaceutical business activities, pharmaceutical bioethics can be a promising response to Brody's call (2012, p. 911) for "more communication and interchange between business ethics and health care ethics than has previously been the case", and that of Robert Califf (former director of the US Food and Drug Administration), who was calling for the establishment of a code of ethics for off-label promotion (McCaffrey, 2017b).

In this paper, I briefly present and analyze the three examples of pharmaceutical bioethics (origins, approach and particularities), and based on their salient features and limits, discuss a way of adapting them to include marketing activities. The focus will be on proposing an approach that enables employees to reconcile competing ethical imperatives (e.g., profits versus public concerns), and the associated organization within companies necessary for the implementation of a bioethics framework to inform and guide practice that avoids being simple window-dressing. Overall this paper argues that it is essential to equip marketers with clear ethical benchmarks, and where it is to the mutual benefit of all to agree on ethical terms for an appropriate and moral practice of pharmaceutical marketing.

Framing the "Doing of Bioethics" by Industry Employees

Aside from the corporate ethics codes that companies may have established (e.g., instituted by pharmaceutical company associations such as PhRMA (2008) in the US, Innovative Medicines Canada (2016), or LEEM (2016) in France), the professional codes of ethics that some employees may follow (e.g., MDs, nurses, lawyers), or internal guidelines and decision trees,

there is for pharmaceutical marketing, a wide spectrum of what Francer et al (2014) call *quality control mechanisms*. These mechanisms come from both industry (International Federation of Pharmaceutical Manufacturers and Associations, IFPMA; and national industry associations) and extra-industry sources (e.g., Ethical Criteria for Medicinal Drug Promotion (World Health Organization, 1988)), and provide high-level ethical guidance to establish norms and inform industry-wide, company-specific, national and/or local practice. But these guidance mechanisms are not operational ethical frameworks that can be used by pharmaceutical employees to guide their daily practices and help solve ethical dilemmas. In fact, until very recently, there has been no theoretical nor operational ethical framework designed for employees working in the pharmaceutical industry. In the following sections, three different tools will be presented – an oath for pharmaceutical marketers, and two principle-based pharmaceutical ethics frameworks for R&D and medical affairs – that are specifically tailored for pharmaceutical employees. It will be argued that in combination, these three tools can lay the foundations for a bioethics framework adapted to the particular context of pharmaceutical marketing.

An Oath for Pharmaceutical Marketers

To guide the practice of pharmaceutical marketers, we developed an oath summarizing the most compelling ethical imperatives that should be followed for ethical communication with consumers (Bélisle-Pipon et Williams-Jones, s.d.). The aim is to take into account various ethical postures so that the practice of pharmaceutical marketers is anchored in: 1) respect for individual consumer autonomy, 2) attention to the population consequences of misinformation and over medicalization, 3) the posture expected by a virtuous person in promoting pharmaceuticals, and 4) the terms of the social agreement stipulating that marketing is justified on the basis of the sharing of benefits (for individuals as well as for industry).

An oath might be seen by some as irrelevant, since in comparison with physicians, pharmaceutical marketers are not part of a formal profession (e.g., nurses, physicians, lawyers) and do not have a fiduciary relationship (i.e., professional-client relations) with the recipients of their communications in the form of an overarching imperative to work in the consumers' best interest. However, pharmaceutical DTCC are legitimated on the grounds that they provide

information and help empower consumers (Hoen, 1998). Further, DTCC can have a major impact on the lives of individuals and shape health-related decision-making (Katsanis, 2016). But it is not necessary to have an explicit fiduciary relationship to develop standards that recognize the societal impact that may occur from the practices of a group of professionals. The scope and nature of the ethical issues raised by DTCC, and the complexity of balancing competing commitments, arguably justify the structuring of ethical imperatives for pharmaceutical marketing in the form of an oath.

The oath is composed of 14 imperatives (see Table 3), each seeking to capture a dimension of pharmaceutical roles, impact and responsibilities related to socially-oriented expectations. These dimensions range from product claims (e.g., presentations about a prescription drug, including benefits and risks) and help-seeking claims (e.g., reasons why a consumer should reasonably talk to a physician about health concerns or symptoms), to in-person or social media interactions with consumers, and the social consequences of over medicalization and societal consequences of misleading communications. The oath is not operational in that it does not provide detailed processes to manage the balancing of competing ethical commitments, as would be the case in a code of ethics, for example; instead, it offers guidance via a general overview of ethical pharmaceutical marketing practices, in addition to providing the "moral bottom line" that must be followed by marketing professionals. By complying with and publicly swearing to fulfill the oath, pharmaceutical marketers should then, we argue, be recognized as reliable sources of information who are trustworthy and integral to improving population health and social well-being. More than wishful thinking, publicly committing to an ethical engagement can have the effect of increasing the adherence by creating the perception of being externally evaluated and judged, and strengthening the will to be recognized as a moral agent (Shu, Gino et Bazerman, 2011; Vincent, Emich et Goncalo, 2013).

We aimed to provide ethical indicators for marketing practice, and to inform future development of marketing-specific theoretical and operational frameworks (Bélisle-Pipon et Williams-Jones, s.d.). It is thus pertinent to explore how this oath could help guide the establishment of benchmarks for pharmaceutical marketing, if complemented by more process-oriented bioethics frameworks and decision-making tools.

Pharmaceutical Bioethics Frameworks

In recent years, two groups have attempted to provide a bioethics framework for the pharmaceutical industry. Coining the terms "pharmaceutical ethics" or "pharmaceutical bioethics", Van Campen and colleagues (Van Campen, Allen, et al., 2015; Van Campen, Therasse, et al., 2015b, 2015a), and Lipworth and Little (2014), offer new theoretical and/or operational lenses with which to understand and resolve ethical issues within the industry. Both propositions use a principle-based approach – inspired by the classic four bioethics principles of Beauchamp and Childress (2013) – as the structure for a practical ethics framework to be used internally, within the company, either by employees or in-house bioethics experts. Table 5 presents, in a comparative manner, the main elements of each group's framework.

Table 5. Overview of two frameworks of pharmaceutical bioethics

	Van Campen et al.	***Lipworth & Little***
Author affiliations	• American industry employees (Eli Lilly)	• Australian academics
Method for establishing the approach	• Practice-based	• Secondary findings from a previous qualitative study
Bioethical taxonomy	• Principle-based	• Principle-based
Conceptual foundations	• Founded on Beauchamp and Childress' 4 principles and Company's mission, vision and values • Aligned with industry ethical guidance documentation	• Derived from Beauchamp and Childress' 4 principles • Adapted for a public and a commercial orientation
Conducted by	• Experts, committees, employees	• Employees, individuals
Aim	• Resolving issues of and providing guidance for company activities • Day-to-day problem solving	• Day-to-day problem solving
Application	• R&D issues	• Medical affairs

A company-based Bioethics Service

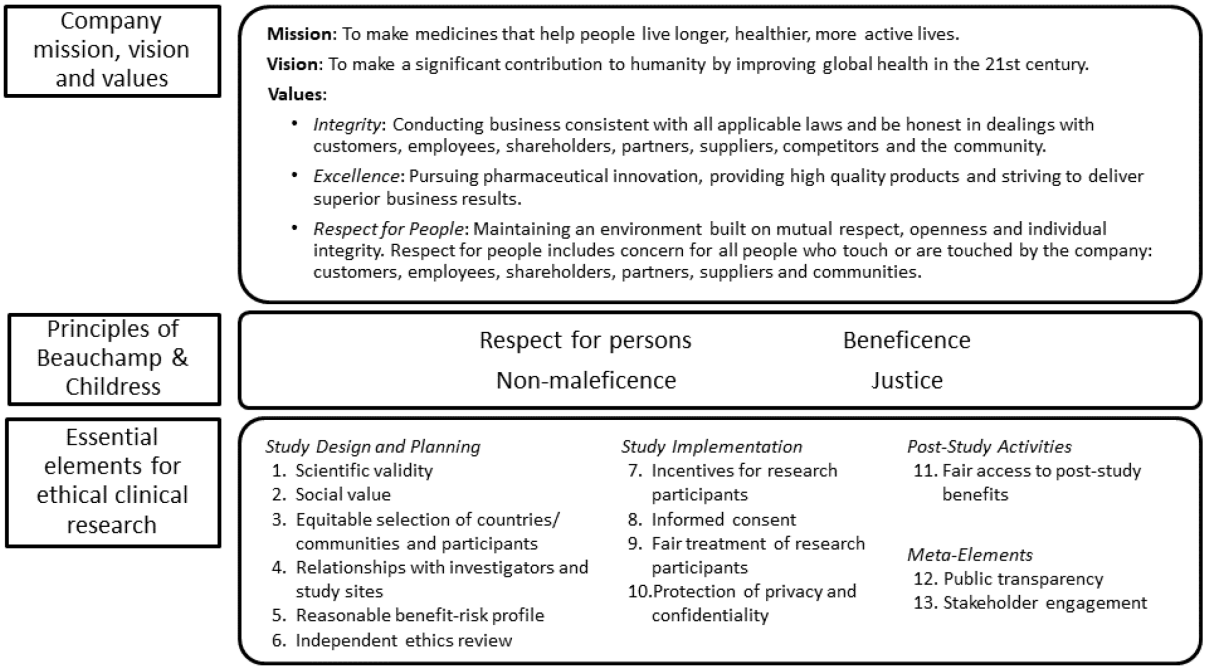
In various publications and scientific conferences, Eli Lilly's pharmaceutical bioethics framework has been presented as a new way to understand and resolve ethical issues surrounding industry activity (Van Campen, Therasse, et al., 2015a). The formalization of this desire to include bioethical considerations in the company's decision-making processes started

in 2008 when Eli Lilly's bioethics program was provided with full-time human resources; it continued to grow thereafter with the establishment of a bioethics framework and a consultation service. Generally, the program aims to "assist employees in identifying and addressing bioethics issues and to engage with internal and external stakeholders on bioethics matters related to the pharmaceutical industry" (Van Campen, Allen, et al., 2015, p. 54). The framework pertains to and serves to address issues related to fundamental research and clinical trials (phase I to IV):

> the framework was developed out of a company need to provide consistent bioethics guidance and a common reference across Lilly's research and development (R&D) enterprise with human participants. It was not designed to provide ethical guidance beyond R&D activities. (Van Campen, Therasse, et al., 2015a, p. 2072)

Figure 13 presents the three content sources that inform the ethical dimensions of the framework: 1) Eli Lilly's specific mission, vision and values (Eli Lilly, 2017); 2) Beauchamp and Childress' four classic principles of bioethics, 3) essential elements for ethical human biomedical research, developed by Eli Lilly following the format of the essential elements of the CIOMS Guidelines.

Figure 13. Content sources informing the pharmaceutical bioethics framework



The framework is intended to serve as "tool for translating ethical aspirations into action – to help ensure human pharmaceutical biomedical research is conducted in a manner that aligns with consensus ethics principles, as well as a sponsor's core values" (Van Campen, Therasse, et al., 2015b, p. 2081). It also serves as a common basis for discussion and as a reference for justifying decision-making.

To operationalize their framework, the company implemented different means, including internal guidance documents on specific topics to inform company's practices and training sessions to support employees (Van Campen, Therasse, et al., 2015a). Another means is "a unique category of bioethics consultation that primarily focuses on pharmaceutical R&D but touches on aspects of clinical ethics, business ethics, and organizational ethics" (Van Campen, Allen, et al., 2015, p. 61). The consultation is confidential and advisory in nature, and works in a similar as institutional review boards (or research ethics committees). Dedicated full-time employees coordinate the consultations and interactions with employees, supported by a Bioethics Advisory Committee composed of senior-level employees from across the company and two prominent bioethicists, namely Tom L. Beauchamp and Robert J. Levine (Van Campen, Therasse, et al., 2015b). The consultation program allows employees to submit their cases and be provided with rapid advice (7 days on average, in 2013) to respond to their ethical concerns. Depending on the requester's needs, the complexity of the question and whether it has already been dealt with previously, the consultation may be delegated (i.e., handled by Bioethics Program employees) or addressed in a plenary meeting of the members of the Bioethics Advisory Committee. The advice formulated can take different forms, including: 1) a list of existing bioethics resources, 2) a summary of the consultation advice, and 3) a formal report (including question, background, assessment, analysis, recommendation). The advice provided is only intended and transmitted to the requester with an educational aim and in a way that facilitates its use by the requester.

An Ethical Framework for Employees

In 2014, two Australian researchers – Wendy Lipworth and Miles Little – proposed an ethical framework for people (from employees to managers) working within the pharmaceutical industry (Lipworth et Little, 2014). Their framework is derived from accidental findings as the authors re-examined the results of a previous qualitative study (based on semi-structured interviews) that sought to understand "what matters" to employees of Medical Affairs departments in Australian pharmaceutical companies (i.e., in terms of transition from science to business environments, how to fulfil their new roles, their opinions on issues regarding drug development) (Lipworth et al., 2013). Building on the "success of principle-based biomedical ethics" in resolving ethically challenging controversies, the goal of Lipworth and Little's new analysis was "to confirm [the] appropriateness [of Beauchamp and Childress' principles] as an organizing framework and describe in detail how they played out in the particular context of the pharmaceutical industry", specifically for clinical and research-related matters. Lipworth and Little found that employees gave two distinct meanings to their obligations: one publicly-oriented (described generally as an "altruistic public focus"); and the other commercially-oriented, which can be summarized as serving their employer's interests, and, more broadly, of an organizational nature (being a good employee). Their findings are summarized in Table 6, with each bioethics principle divided between specific obligations to the public and to the company. Due to the content of the initial questionnaire, autonomy did not "spontaneously" emerge from participant insights as a core principle, which is recognized as a limitation by the authors. Nonetheless, the authors argue that this the four principles of bioethics could "help those in the pharmaceutical industry, and those interacting with the industry, to conceptualize and work through ethical dilemmas that emerge in the context of commercial drug development" (Lipworth et Little, 2014, p. 25).

Table 6. Key elements of Lipworth & Little's Principle-based Approach

Principle \ Ethical Orientation	Publicly Oriented	Commercially Oriented
Beneficence	• Altruism, idealism, commitment to the well-being of patients and the community	• Care of colleague • Care of the company • Being a team player

	• Contribution to biomedical scientific knowledge	
Nonmaleficence	• Safety of patients and research participants	• Ensure efficient processes by careful preparation • Avoid damaging company reputation
Justice	• Consideration for national resources and aim for equitable resource allocation • Inclusion of all populations • Fair play with external stakeholders and regulation	• Commitment to shareholders • Desire to be treated fairly by external stakeholders
Autonomy	• *Did not emerge from the interviews*	• *Did not emerge from the interviews*

Discussion

Defining and using a bioethics framework specific to the pharmaceutical industry is an interesting approach to understanding and capturing the ethical rationales that should guide and pave the way for ethical conduct within the industry. Beyond simple compliance to moral or legal rules and imperatives, ethical frameworks specific to the pharmaceutical can allow "analytic flexibility or reflection" (Lipworth et Little, 2014, p. 24) so that context can be appraised in such a way that conduct and decision-making are aligned with compelling ethical requirements. Ethical deliberation is key for those working in the pharmaceutical industry, to ensure that they are meeting the competing imperatives expected from them, i.e., profits and pro-social expectations.

Before making use of and integrating the salient features of the three aforementioned approaches (i.e., the oath and two ethics frameworks) to pharmaceutical bioethics, it is important to point out that the two frameworks were limited in scope and concerned only with research, clinical and medical activities. Specifically, they encompass R&D activities and not all aspects of the drug life cycle, from discovery and development, through clinical trials, to marketing approval, market entry and, if necessary, market withdrawal. The application of these two frameworks to marketing practices will thus necessitate some adaptation: first, by using the pharmaceutical marketing ethics oath as a basis for contextualizing marketing practice; second, by clarifying and reconciling the dual commitments in marketers' practices; and third, by reflecting on the deployment of the frameworks with regards to the company's practice and organizational chart.

Contextualizing Frameworks to Marketing Concerns

As neither pharmaceutical bioethics framework was developed with marketing concerns in mind, but instead restricted to biomedical issues, it is necessary that they be adapted; and the *Pharmaceutical Marketing Oath* we developed (Bélisle-Pipon et Williams-Jones, s.d.) can provide the necessary contextual insight. Table 7 presents how the oath's ethical imperatives may be translated into Lipworth and Little' principles (in their reinterpretation of Beauchamp and Childress') and Van Campen et al ethical essential elements. Categorizing each imperative may probably be interpreted differently by others, but the present classification has been made according to the matching of those which seem particularly necessary in the context of marketing ethics.

Table 7. Aligning ethical imperatives of the pharmaceutical marketing oath with Lipworth and Little's principles and Van Campen and colleagues' ethical essential elements

Imperatives for pharmaceutical marketing[37] *(Bélisle-Pipon & Williams-Jones)*	**Which principles should it inform?** (*Lipworth & Little*)	**Which ethical essential elements should it inform?** (*Van Campen et al.*)
1. respect hard-won scientific gains and knowledge on which pharmaceutical drugs have been developed, approved	• All	• Scientific Validity • Reasonable Benefit-Risk Profile Presentation
2. ensure presentation and review of scientific evidence or interpretation are honest and accurate; ensure information provided / used in DTCC is unbiased and does not knowingly mislead	• Autonomy	• Informed Consent
3. remember that DTCC is legitimized because it provides useful and unbiased information for informed decisions; do not frame DTCC so consumers consider as being true claims that are not relevant and/or beneficial	• Autonomy • Non-maleficence	• Informed Consent • Social Value
4. do not overemphasize product's benefits; ensure complete and accessible presentation of risks and adverse events to consumers	• Autonomy • Beneficence	• Reasonable Benefit-Risk Profile Presentation • Informed Consent
5. do not foster medicalization of health or encourage disease-mongering; do not try to convince people that they are sick; do not present a product as prevention while it is rather fostering disease-mongering.	• Non-maleficence • Autonomy	• Reasonable Benefit-Risk Profile Presentation • Informed Consent

[37] For convenience, the imperatives have been synthetized from their original formulation, which can be found in ''our article.

6. have dual obligations: towards employer to help make profitable their product(s); and towards consumers, to ensure DTCC only fosters the 6 rights to medication (right patient, right medication, right reason, right dose, right route, right time)	• All • *Legitimize having dual commitment or ethical orientation to all principles*	• Social Value • Reasonable Benefit-Risk Profile Presentation
7. be careful marketing lifestyle and life-threatening medications; provide only relevant and scientifically proven-facts; do not take advantage of context that is unfairly conducive to product sale	• Non-maleficence • Autonomy	• Scientific Validity • Informed Consent
8. make sure not to exclude alternatives to medications, nor to present them as less advantageous than pharmaceutical solution	• Non-maleficence Beneficence	• Scientific Validity • Informed Consent
9. respect consumer privacy, do not seek sensitive information; avoid co-opting relatives to change consumer perceptions	• Non-maleficence	• Protection of Privacy and Confidentiality
10. ensure that DTCC are clearly identified as such, not hidden as a public health campaign	• Non-maleficence	• Public Transparency
11. ensure conflicts of interest are declared when involving healthcare professionals or others in DTCC; never encourage or participate in corrupt practices, professional misconduct	• Non-maleficence	• Public Transparency • Stakeholder Engagement
12. remember that drugs represent significant costs to patients and society, can affect family and economic stability and generate collective costs	• Justice • Beneficence • Non-maleficence	• Social Value
13. remember that they are members of society, with power of persuasion that can cause serious consequences if not deployed for beneficial purposes	• Beneficence • Justice	• Social Value
14. by complying to the oath, be recognized as trustworthy and reliable source of information for improving health and social well-being	• All • *Justifying marketing practices*	• Social Value • Public Transparency

From this comparison, it is possible to see that the oath's imperatives should primarily inform concerns about non-maleficence (n=11), autonomy (n=8) and beneficence (n=7), and then justice (n=4). It should come as no surprise that non-maleficence prevails, considering that DTCC is most often criticized for conveying biased information and contributing to the medicalization and over-medication of consumers. The emphasis on consumer information and empowerment, which is used to legitimize DTCC, explains why benevolence and autonomy are also very important. The dimensions of justice within the ethics frameworks are in relation to the costs that this can pose to consumers and third-party payers, and thus relevant to a more limited number of imperatives. With regards to the essential elements, informed consent (n=6) is the most prevailing element followed by social value (n=5) and reasonable benefit-risk profiles (n=4). Public transparency and scientific validity are pertinent for some specific

imperatives (n=3) and finally, stakeholder engagement and protection of privacy and confidentiality each inform one imperative. Considerations relating directly to research and clinical trials were excluded, hence the absence of essential elements #3, 4, 6, 7, 8 and 11 outlined by Van Campen and colleagues (see Figure 1).

Three imperatives relate to all principles. 1) Imperative 6 recognizes employees' dual commitment, and so corroborates the dual ethical orientation for each principle presented by Lipworth and Little; 2) Imperative 1 stresses the importance of scientific knowledge, which has an impact on all ethical principles; and 3) Imperative 14, as a concluding statement about the trustworthiness and legitimacy of those engaging in DTCC, informs how all principles should guide ethical practice in pharmaceutical marketing.

Reconciling Competing Ethical Imperatives

One important challenge of pharmaceutical bioethics is how to balance competing ethical commitments. Van Campen and colleagues (2015a, p. 2071) acknowledge that a company has important ethical responsibilities towards all those "who may be affected by the company or its products" – including patients, healthcare providers, payers, shareholders, regulators, health authorities, etc. – and specify that the nature of the responsibilities and the actions to be taken vary according to the stakeholders. Lipworth and Little recognize, in their presentation of the four principles, the dual commitments (or ethical orientations) to which pharmaceutical industry employees must comply. The authors recognize that employees must in practice "balance the communal responsibilities that [they owe] to the general public (otherness) against those owed to [their] company (firm-ness)" (Lipworth et Little, 2014, p. 29). Ethical dilemmas can thus be presented in terms of the ethical orientation of conflicting principles, allowing for a better grasp of the complexity of commitment which an employee faces daily. For instance, public-oriented beneficence can be opposed to commercial beneficence when an employee is confronted with the design of a promotional campaign that may promise to be very effective at increasing sales, but which conveys half-truths and misleading information. Table 8 presents the integration of marketing concerns and imperatives with the ethical orientation of each principle.

Table 8. Adapting Lipworth and Little's Principle-based Framework to Pharmaceutical Marketing Bioethics

Principle \ Ethical Orientation	Publicly Oriented	Commercially Oriented
Beneficence	• Altruism, idealism, commitment to the well-being of patients and the community • Contribution to patient knowledge and informed decision-making	• Care for marketing effectiveness • Care of colleagues • Care of the company • Being a team player
Nonmaleficence	• Avoid compromising patient safety • Avoid disease-mongering • Avoid medicalizing patients	• Ensure efficient practices by careful preparation • Avoid damaging company reputation
Justice	• Consideration for national resources, aim for equitable resource allocation • Inclusion of all populations • Fair play with external stakeholders and regulation • Care for vulnerable populations	• Commitment to shareholders • Desire to be treated fairly by external stakeholders
Autonomy	• Foster informed consent and decision-making • Foster patient empowerment	• Respect for creativity in deployment of marketing practices

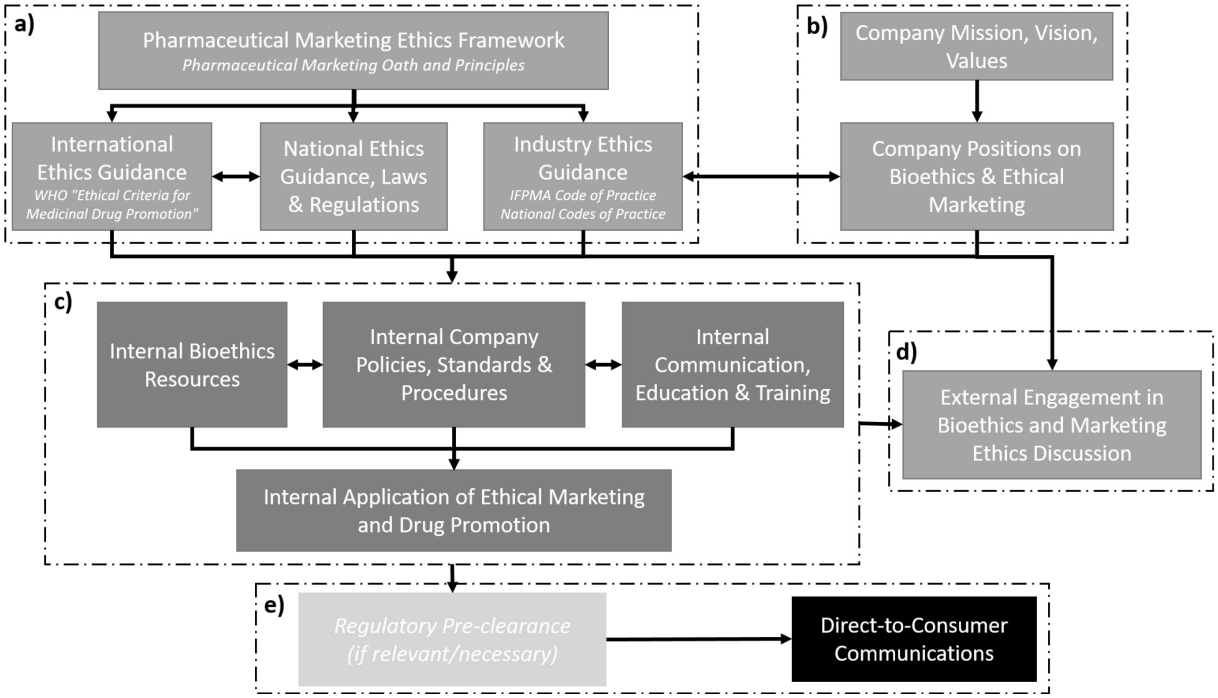
This dual ethical orientation of the principles may serve to guide employer decision-making in the specific context of marketing practices. As marketing employees currently do not have any DTCC-specific ethical guidance for their practice, it is not surprising that corporate interests are dominant since there is no deterrent to pursuing questionable practices. By contrast, ethical guidance could play an important role of advising and guiding marketers to consider the pro-social and ethical dimensions of their practice. Considering that ethical principles may function as explanations for action (Berker, 2017), they can inform what is considered an ethical practice and based on which criteria and features the practice is to be evaluated. In other words, principles give substance and highlight the properties of an action (or a practice) and the features of the system in which it takes place that makes it possible to contextual the degree of rightness or wrongness of an action (Berker, 2017). The fact that both frameworks and the oath stress the importance of the multiplicity of stakeholders and the complexity of a company's (and employee) responsibilities towards is recognition of the importance of contextualization and appropriate characterization of competing commitments.

Organizing a Pharmaceutical Marketing Bioethics Within Industry

In addition to having a set of principles relevant to employee practice, the inclusion of bioethics within a company is commendable and necessary; this is one of the most interesting highlights in the work of Van Campen and colleagues. Beyond simply establishing a framework, Eli Lilly's Bioethics Program aims at aligning business conduct with ethical expectations by: 1) complying with hetero-regulation (ethics guidance, law and regulation); 2) developing internal guidance on specific ethical matters; 3) informing company policies; 4) providing bioethics consultations; and 5) training personnel. According to Van Campen and colleagues, the organizational resources and the consultation model support employees in their ethical deliberations and "provide employees with a consistent foundation for engaging in discussions external to the company on matters relating to bioethics and research integrity" (Van Campen, Therasse, et al., 2015a, p. 2076).

Reapplying the salient organizational and implementation considerations to marketing and drug promotion, Figure 14 presents how marketing ethical guidance may be structured by being aligned with both hetero-regulation and company self-regulation. The flowchart is divided into 5 sections: Section a) represents the overarching guidance, here proposed as a *Pharmaceutical Marketing Ethics Framework*, as well as international, national and industry ethics guidance and national laws and regulations. This guidance represents the company's hetero-regulation, which may interact with b) the company's self-regulatory position. Sections a) and b) are mainly in dialogue through industry ethics guidance (Francer et al., 2014); but they both also influence c) the company's policies and procedures, and are in relation with d) external commentators (such as the academic and professional literature). Section c) represents all the internal resources that support employees' ethical conduct, so that e) ethical DTCC is practiced. Section e) represents the final output, i.e., the actual DTCC campaigns that may be generated, and comprises a last filter for jurisdictions and contexts that may have voluntary and/or compulsory DTCC pre-clearance.

Figure 14. Pharmaceutical Marketing Ethics Organizational Flowchart



Adapted from Van Campen et al (2015a) and Francer et al (2014)

In this organisational flowchart, a) and b) represent the ethical guidance that must inform c) daily business activities and decision-making processes. The final output of the flowchart are the actual communications and campaigns that will end up reaching consumers, and if jurisdictionally relevant, may need to be pre-screened by a certain authority (regulatory agency, independent or industry-affiliated organization). Embedded throughout the flowchart is the importance of including third-parties and open dialogue with external entities; hence a), b) and c) are linked to d) by seeking discussion with stakeholders about ethical and marketing issues.

No matter how ideal an organization may seem, in practice, to be efficient and to achieve the desired results it is necessary that the organizational structure nurtures employees' ethical decision-making, so that ethical deliberation is part of accepted business practices. This is especially important since marketing practices may trigger important conflicts of commitment: promotional efforts have as a main interest to drive the sales of pharmaceutical drugs and marketing practices seek to shape markets for their products; but they often present themselves

with a benevolent rhetoric, where it is patient interest for genuine information and empowerment that is conveyed as having priority (Bélisle-Pipon et Williams-Jones, s.d.).

Limits

Adapting pharmaceutical bioethics frameworks designed for R&D and Medical Affairs to the particularly context of marketing and DTCC obviously has some limitations. As stated by Van Campen et al (2015a, p. 2072), "given these complex relationships and concomitant ethical responsibilities, navigating ethical decision-making can be challenging for a sponsor using current ethics resources as a guide." The very same can be said about marketing practices, so the proposed pharmaceutical marketing ethics framework must be seen as a first step, necessarily followed by others, towards empowering the ethical competencies of marketing professionals.

The Limits of Broadening Frameworks that are R&D-oriented

One important limit of the proposed pharmaceutical marketing ethics framework, as well as the other two more general pharmaceutical bioethics frameworks, is that they are not yet comprehensive and only focus on a specific part of industry practices. The industry does not work in a silo, and although business activities (such as R&D and marketing) may be compartmentalized (into departments or business units), they all work (or should) towards the goal of developing safe and effective drugs from which the sale will make the company profitable. One must not be naïve; the pharmaceutical industry, through its various activities, can induce adverse social effects. They may, however, be prevented by careful ethical reflection and resolution of the underlying issues, which are often systemic and not specific to a particular industry practice. It is therefore important to consider the drug life cycle in its entirety to address these ethical issues.

Marketing and promotion are extremely important and should not be isolated, given that they are fundamental to the business framework of companies (Bélisle-Pipon et Williams-Jones, 2015a). These commercial issues are important, even if they can be challenging or even in some cases taboo. An efficient and comprehensive pharmaceutical bioethics framework would thus benefit from not being restricted only to R&D or marketing, for example, and instead recognize

that "the industrial sector is implicated in a range of ethical dilemmas; social, political, cultural, and economic challenges necessarily accompany both the scientific and commercial development of new technologies" (Brian, 2012, p. 32). The current development of specific frameworks should thus be seen as the first step in the development of a comprehensive framework, one that recognizes that the ethical challenges are all intertwined, and when dealt with systematically, support all business activities.

Avoiding Window-Dressing

An important concern may be that this new focus of bioethics on pharmaceutical ethics is or can become nothing more than window-dressing for the pharmaceutical industry. That is, this new specialty of bioethics may be instrumentalized to help a company appear more ethical and so improve public opinion, instead of being used as a means for the company to actually address the real-world challenges of aligning interests of profitability with the interests of the society as a whole (e.g., equitable access to safe and cost-effective medications, promotion of rational use of medicines that does not limit options to pharmaceutical solutions). As noted by Takala, this may be an important concern for some scholars since "Window dressing is still very much looked down on by bioethicists of all persuasions, but *with the growing desire of business corporations to engage in ethical discussions* it seems likely that bioethics consultancy and related activities are a thing of the future." (Takala, 2005, p. 385-386)

The establishment of a bioethics program within Eli Lilly is praiseworthy, however this practice is not widespread and its impact on business practices is still uncertain. The question of window-dressing leads to reflection on the extent to which employees are actually free, and encouraged by their employer, to use ethical deliberation and act accordingly. For Brody (2013), the answer is easy: "I may agree or I may disagree with [Van Campen's] ethical thinking on a variety of issues, but at least we know fully where her loyalties lie. She's a paid Lilly employee, and we must imagine that the minute that her activities were judged by Lilly to be bad for business, she'd be out the door." Brody might be considered overly critical and pessimistic – alongside other scholars, such as Elliott (2003, 2004) – of any kind of ethics done within the industry[38],

[38] Elliott (2012) was also concerned about the risks of publishing industry-funded bioethics articles and more generally raising the question whether an industry-funded bioethics is a bioethics that we can be trustworthy.

whether by employees specializing in bioethics or by employees in general. Evans (2010) goes even further and questions the very legitimacy of doing bioethics within a company, using confidential (and opaque) decision-making processes that are presented as being done on behalf of the public, and which leave it to the employees to decide what is best in ethical and pro-social terms. The authenticity of such an approach is therefore questioned.

In the absence of any binding mechanism or rule (formal regulation or self-regulation) to which companies would be obligated (or oblige themselves) to mitigate and resolve bioethical issues, Brody's and Elliott's concerns remain pertinent, especially when one considers that "[i]ndustry interests are the most significant and probably hardest to address" (Lemmens, 2013, p. 174). None of the frameworks presented here provide detailed practical guidance on how to bind companies to ensure that they seek genuine resolution for their ethical issues, or empower employees to succeed in such a culture change. This is, nevertheless, a step in the right direction, so much so that the application of bioethics within the industry must not only entail cosmetic changes (Elliott, 2003; Rasmussen, 2006), but also have a good chance of changing industry practices by informing and equipping its employees. And this means having a corporate culture that will "walk the talk" and not use bioethics as window-dressing.

Conclusion

Pharmaceutical bioethics addresses tensions that are relatively new in bioethics, as one of its most salient features is the commitment to integrating companies' competing commitments (i.e., profits and pro-social expectations) with a more elaborate set of ethical tools that recognizes the dual role (financial and therapeutic) of the industry. But how can or should an employee in the pharmaceutical industry in general, or in marketing in particular, determine which competing solution may be the most appropriate? This is the very objective of the articulation of a bioethical framework that can be used by pharmaceutical industry employees to resolve ethical challenges and to reduce moral distress and burdens associated with complex ethical matters. However, to be successful and relevant, it must go beyond the traditional focus on research and clinical ethics issues (Wolpe, 1998), by taking account of the whole spectrum of pharmaceutical industry activities and business practices. The scope and variety of questions that can touch on aspects of business and organizational ethics must be integrated into a pharmaceutical (bio)ethics. In so

doing, a pharmaceutical bioethics framework must include attention to the commercial imperatives (e.g., companies must be profitable and have financially sustainable operations) that are often lacking in bioethics scholarship on the issue. This competing dimension needs be applied throughout the drug life cycle, from conception to research and development (R&D) and commercialization of the product. Further, pharmaceutical bioethics must promote genuine ethical resolution, even of challenging and taboo issues within the industry, and this means that companies must allow their employees to raise ethical concerns without fear of reprisal, and when relevant, give them the means and the space for reforming certain activities at the core of the pharmaceutical business model. Companies must therefore believe in and foster an ethical culture that promotes positive change in line with ethical guidance, even when it challenges current practices.

Pharmaceutical bioethics can provide a new and better understanding of the ethical concerns the industry is facing, and so complement work being done in related areas of applied ethics, such as business and organizational ethics (Leisinger, 2005; West, 2012) to support businesses in resolving their ethical issues. As the first concrete efforts to outline an ethical framework adapted for use within the pharmaceutical industry, the frameworks presented by Van Campen and colleagues, and Lipworth and Little, contribute to advancing ethical reflection in this sector, and can arguably also be adapted to the marketing context. But considering the restricted scope of the pharmaceutical bioethics approaches used in the frameworks presented in this paper, we are still far from the necessary comprehensive conceptualization and application of ethics within the industry. Yet, in presenting their frameworks, Van Campen and colleagues, and Lipworth and Little have done a great service to bioethics, in setting the field for further research into frameworks that can help the pharmaceutical industry achieve an effective balance between social and commercial imperatives.

Much work still remains, then, to move: 1) from a theoretical framework to an epistemically sound extension that allows for a more comprehensive bioethics, and 2) from an operational framework to a real transformation of industry practices and business models. What may be needed is a framework, or multiple frameworks, that can serve the needs for conceptual and critical inquiry by academics, and as an ethical compass for employees and decision-makers

(Magnus, 2002). Such a framework(s) should enable the challenging of elements that may currently appear to be untouchable, delicate or foundational to the activities or to the business framework of the industry. What would be the purpose of ethics otherwise? After more than fifty years of existence, bioethics has only begun to have the means to support ethical reflection and decision-making within the industry. This is an important turn since numerous bioethical concerns related to pharmaceuticals stem from daily business activities. By empowering employees to adopt a more ethical practice, pharmaceutical bioethics targets the core of the problem, by making the employees part of the solution.

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Considérations finales

L'objectif de cette discussion était d'arriver à traduire les conclusions portant sur l'hétérorégulation des pratiques de CDCM provenant des cas à l'étude en des pistes de réflexion et des balises pour guider la pratique des employés au sein de l'industrie. Cela s'est fait en deux temps : d'abord par l'établissement de repères éthiques spécifiques aux CDCM sur la base des grandes théories morales, puis par l'élaboration et la proposition de développement d'un outil conceptuel, la bioéthique pharmaceutique, habilitant à concilier les impératifs commerciaux et sociétaux *sine qua non* à l'existence et à la justification des pratiques de CDCM.

De l'analyse des pratiques de l'industrie et de l'état des « règles du jeu » chargées de les baliser, des limites actuelles à l'hétérorégulation et de recommandations pour les bonifier (Partie II), il a été possible de se pencher sur les pratiques acceptables et attendues de CDCM et les bases sur lesquels devraient être fondée l'autorégulation de l'industrie (Partie III). Il est important de souligner que le but n'est pas de faire reposer la responsabilité que sur les seules épaules des employés, mais de reconnaître un contexte complexe où la responsabilité se partage entre une variété d'acteurs (incluant, sans s'y limiter, l'industrie et les régulateurs) dont les comportements et les pratiques éthiques ont un impact sur le quotidien et les pratiques des employés. Conséquemment, il convient d'indiquer que cela requiert un grand investissement des compagnies à s'engager dans une démarche éthique visant des comportements corporatifs plus éthiques ainsi qu'à outiller et soutenir leurs employés. À ce stade, l'engagement éthique proposé au Chapitre 6 ainsi que le cadre postulé de bioéthique pharmaceutique au Chapitre 7 ont principalement une valeur heuristique et dialogique. Ces propositions établissent des paramètres pour une discussion informée ayant lieu entre les principaux intéressés et l'industrie en général pour l'établissement de modalités autorégulatrices. Cette discussion sera essentielle en vue d'inclure l'industrie dans une plus large réflexion sur l'éthique du marketing pharmaceutique.

Ces propositions rencontreront évidemment de la résistance et des réticences. Cependant, il est présumé que l'engagement éthique et, plus largement, la bioéthique pharmaceutique devraient être intéressantes et avantageuses pour l'industrie, comme des moyens pour parvenir à mieux

baliser ses pratiques et à plus facilement intégrer les attentes pro-sociales. De cette conformité des pratiques aux repères éthiques découleraient une série d'avantages qui rendent plausible et pragmatique l'adhésion volontaire des compagnies à des repères éthiques et à la transformation de ces pratiques. Cela inclut, sans s'y limiter : 1) un niveau de confiance publique accrue que peut générer un engagement éthique socialement reconnu; 2) une amélioration des relations avec les régulateurs; 3) une augmentation de l'efficacité des procédures d'évaluation et de dissémination des activités marketing par l'évitement de la nécessité pour les régulateurs de renforcer leur cadre règlementaire et de surveiller de plus près les pratiques marketing; et 4) la fin des compensations à verser dans le cadre de poursuites intentées pour des pratiques marketing délétères. À cela s'ajoute l'avantage compétitif pour les premières compagnies qui se conformeraient à ces propositions, qui bénéficierait d'un capital de confiance supplémentaire. Et, lorsqu'une majorité des compagnies auront intégré la bioéthique pharmaceutique dans ses pratiques, cela deviendra une attente pour l'ensemble du secteur et donc une nécessité d'y adhérer volontaire plus tôt que tard.

La Partie II a mis en lumière l'importance de la bonification de l'hétérorégulation, et les « règles du jeu » et les attentes pro-sociales doivent impérativement être clarifiées. Cependant, il est postulé ici que l'autorégulation est la voie qui apparaît comme étant la plus performante, au sens où elle est l'une des moins explorées (une bioéthique spécifique aux considérations marketing et visant à soutenir les employées est assez novateur), et surtout c'est un des moyens de réguler les pratiques où il y a le plus à faire. Cela étant, le constat demeure clair, si l'industrie n'est pas disposée à volontairement et efficacement autorégulées ses pratiques en conformité aux repères éthiques, alors la réponse hétérorégulatrice se devra d'être plus stricte afin de pallier aux manques et baliser les comportements corporatifs en termes de marketing pharmaceutique.

Bien que beaucoup reste encore à faire, les réflexions et les propositions découlant de cette thèse sont des pistes contribuant à faire en sorte que profits et considérations éthiques puissent être conciliés au bénéfice mutuel de l'industrie et de la société. En ce sens, l'énonciation de la bioéthique pharmaceutique est une façon de partager un langage commun, mais surtout d'inclure

l’ensemble des acteurs (industrie, régulateurs, société, bioéthiciens, etc.) dans la recherche et la mise en place de solutions permettant de concilier les impératifs commerciaux et sociétaux.

Conclusion

Au cours des dernières décennies, un large éventail de nouveaux dispositifs de CDCM a fleuri. Chacun révolutionnant la façon dont sont rejoints les consommateurs en permettant désormais, d'interagir avec un nombre toujours croissant de consommateurs. La légitimation de ces dispositifs est demeurée inchangée, soit de procurer des informations essentielles aux consommateurs afin qu'il puisse faire des choix éclairés par rapport à leur santé. Dispositif fortement contesté, les CDCM sont loin d'avoir effectivement eu les impacts positifs allégués sur les consommateurs. Rhétorique bienveillante à l'égard des consommateurs ne s'est pas avérée à la hauteur des effets putatifs bénéfiques des CDCM. Constat lié au rôle des pratiques marketing dans le modèle d'affaires des entreprises, soit de les rendre profitables par l'accroissement des ventes de ses produits. Comme il s'agit là de son objectif premier, c'est donc une pratique particulière et contestée de par la dimension commerciale sous-jacente qui la guide.

Pour pallier à cette situation, un ensemble de recommandations et de repères éthiques ont été énoncés afin de concilier cette pratique à la finalité promise. Quoique la posture de la thèse est que l'industrie n'est pas forcément l'acteur le mieux placé pour informer, éduquer et autonomiser les consommateurs, et ce en raison de son conflit d'intérêt financier, l'industrie dispose des dispositifs et des stratégiques les plus performants pour rejoindre efficacement les consommateurs. C'est donc une stratégie de moindre mal (voire de réduction des méfaits) qui est adoptée en proposant un ensemble de repères éthiques pour rendre plus moralement adéquates ces pratiques en ciblant les employés, jusqu'alors loin du radar de la bioéthique. Pour parvenir à concilier cette tension entre profit et contribution à la santé humaine, il a été suggéré d'agir à la fois sur l'hétérorégulation des pratiques, par les agences règlementaires, et sur l'autorégulation de l'industrie, plus particulièrement des pratiques de ses employés œuvrant au marketing de ses produits.

Comprendre, pour pallier et recommander

Dans la Partie II de cette thèse, l'accent fut mis sur l'hétérorégulation comme dimension essentielle pour baliser les pratiques de l'industrie et établir « les règles du jeu » auxquelles le

marketing doit se conformer pour des pratiques acceptables. Ont donc été étudiés des cas réels et exemplatifs des pratiques ayant cours afin d'analyser les impacts de l'état actuel de la règlementation et plus largement, l'adéquation entre les pratiques de l'industrie et la finalité méliorative revendiquée. À cet effet, dans le Chapitre 3, il a été vu qu'au-delà de la rhétorique présente dans les CDCM les considérations liées au choix et à l'autonomie peuvent être instrumentalisées par le marketing de sorte à résonner comme étant pertinentes dans la réalité de l'individu au détriment de sa capacité à faire des choix informés. Il a été notamment suggéré que la régulation prenne en compte une vision de l'autonomie bien au-delà de celle simpliste promue par le marketing : soit que plus d'informations (peu importe sa qualité et sa neutralité réelle) favorisent l'agentivité et la capacité de choix des consommateurs.

Il a été illustré dans le Chapitre 4 que celles-ci utilisent des mécanismes similaires aux campagnes promotionnelles faisant en sorte que les CDCM ont moins une qualité informationnelle et éducative qu'un moyen de familiariser les consommateurs à des gammes de produits et des solutions pharmaceutiques. Souvent le contexte a un impact sur cette familiarisation des consommateurs, notamment par un éthos populaire et réceptif aux solutions pharmaceutiques dans lequel s'ancre une campagne, qui n'est pas prise en compte par les régulateurs. Également, les informations véhiculées élargissent le public cible, notamment par des autodiagnostics présentant les consommateurs comme étant plus à risque qu'ils ne le sont vraiment. Ensuite, de façon plus insidieuse, les critères mêmes d'acceptabilité des CDCM, pourtant souvent présentés de façon neutre et procédurale comportent leur lot d'ambigüités. En effet, ils sont souvent assez vagues et sujets à interprétation d'où l'importance de clarifier les attentes par une documentation plus précise. De plus, que l'usage de CDCM via les médias sociaux ne soit que très peu encadré porte à réfléchir, considérant les dimensions interactives de ce type de dispositifs, rend d'autant plus crucial que les régulateurs à établissent des normes pour pallier à ce manque.

Au-delà de la question de légitimité de l'industrie à communiquer directement aux consommateurs, une limite a été posée, au Chapitre 5, quant aux interactions en présentiel qui ne sont pourtant pas régulées à l'heure actuelle. Considérant que ce type d'interactions viennent interférer avec les modèles convenus, les interactions en présentielle devraient être limitées aux

relations entre les consommateurs et leurs professionnels de la santé (non rémunérés par l'industrie). Il a été notamment énoncé que, dans ce cadre, l'autorégulation telle que pratiquée actuellement n'était pas la meilleure avenue et que les agences règlementaires devraient se charger d'encadrer ce type de pratiques. Il est donc préférable de restreindre les communications en présentiel à des organisations sans lien avec l'industrie, et de mettre sur pied des initiatives d'éducation continue des consommateurs, exempte de conflits d'intérêts. Une énonciation et organisation de ce type de modalités d'information auprès des consommateurs a été formulée, autant qu'un appel aux régulateurs à s'intéresser davantage à ce type de pratiques.

À l'aune de l'étude de ces cas et de la littérature, un constat important se dégage de la Partie II relativement à une surveillance lacunaire des pratiques. Les mécanismes régulatoires sont beaucoup moins sophistiqués en ce qui concerne les activités ciblant directement les consommateurs que celles ciblant les professionnels de la santé. Cela est paradoxal considérant que les patients représentent une population dont la littératie en santé est bien moins développée que celle des professionnels de la santé ce qui les rend moins équipés et informés et potentiellement, plus vulnérables face à des communications provenant de l'industrie. Dans la majorité des juridictions, les CDCM ne sont pas soumises à une approbation règlementaire (au mieux elle est volontaire et elle est opérée par l'industrie ou des agences indépendantes, souvent sans pouvoir de contrainte réel), et les mécanismes de contrôles sont largement inefficaces. Toutefois, malgré les prétentions des organismes régulatoires, les études de cas du Chapitre 4 ont bien illustré qu'ils n'ont, jusqu'à présent, pas été en mesure de les réaliser,, soit pour des *a priori* politiques favorisant la dérèglementation, des restrictions budgétaires ou simplement par son incapacité de suivre les avancées technologiques et de réguler les différentes formes de campagne d'information.

Portée et limites des cas étudiés

L'objectif de l'analyse de cas réels était de parvenir à un portrait des grands enjeux découlant de l'état actuel de l'encadrement des pratiques de CDCM. Pour ce faire un exemple de dispositif par type de CDCM a été analysé. L'objectif n'était ni de parvenir à l'exhaustivité des cas ou des enjeux, mais bien de dégager les grandes tendances. Dès lors, la sélection s'est faite sur la base

de cas exemplaires et représentatifs permettant de démontrer un éventail des enjeux éthiques que soulève chaque dispositif marketing.

Une seconde particularité est le fait que les dispositifs sont souvent utilisés en synergie. Ainsi, une campagne marketing peut inclure plusieurs CDCM, c'est pourquoi les cas exemplifiant un certain type de CDCM à l'étude ne pouvaient être complètement mutuellement exclusifs. Donc dans un cas, bien qu'il pût y avoir plus d'un type de CDCM en action, le dispositif qui était central à la campagne (par exemple, le site web *40desplusde40* ou les « dates ») était celui qui a fait l'objet d'une analyse. Par exemple, alors que dans le Chapitre 3, les éléments centraux des campagnes sur la suppression des menstruations étaient diffusés dans des médias traditionnels, certaines campagnes faisant la promotion de contraceptifs hormonaux référaient à des sites web. Certains de ces sites web contenaient des outils autodiagnostics, similaires à celui de la campagne sur la dysfonction érectile *40over40* (Chapitre 4). Toujours dans le cadre de la campagne *40over40*, c'est une annonce télévisée qui référait à un dispositif de eCDCM, cela étant le principal objet d'analyse dans le chapitre était le site web en question.

Également, une autre limitation a trait à la diversité des médicaments et de leur indication thérapeutique ayant fait l'objet d'une étude de cas. Deux médicaments (dysfonction érectile et suppression des menstruations) sur les trois promus dans les CDCM étudiées étaient des médicaments dits de « style de vie » (*lifestyle drugs*), c'est-à-dire des médicaments ciblant davantage la convenance plutôt qu'une réelle nécessité médicale. Ce choix n'était pas délibéré, mais découle probablement du fait que ces médicaments font l'objet en proportion de plus d'efforts marketing que d'autres produits. En effet, ils peuvent être publicisés auprès de populations plus vastes, car généralement en bonne santé, les ventes des produits qui en découlent justifiant des investissements initiaux plus conséquents. Bien que certains patients souffrent réellement de conditions médicales pour lesquelles ces médicaments peuvent avoir un effet intéressant, la valeur thérapeutique et la valeur pour la société de ce type d'investissements restent discutables. Cette tension entre valeur thérapeutique et sociale est d'autant plus intéressante pour élargir la portée de l'analyse de l'éthique du marketing pharmaceutique, et devrait être mieux prise en compte dans l'évaluation de la pertinence et acceptabilité des pratiques de l'industrie.

Finalement, les cas ont principalement traité de considérations pertinentes aux États-Unis et au Canada; il y a ainsi une certaine limite juridictionnelle aux cas sélectionnés. Cependant, les implications et recommandations découlant de l'analyse ne sont pas que pertinentes au contexte nord-américain. Les deux juridictions représentent des cas paradigmatiques : les États-Unis sont l'extrême en matière de permissivité des CDCMs alors que le Canada est assez représentatif des pays ayant partiellement relaxé sa régulation. Ces deux pays sont donc d'autant plus intéressants pour tirer des conclusions. Qui plus est, il convient de mentionner, considérant d'une part que les eCDCM sont transfrontalières et peuvent virtuellement rejoindre l'ensemble de la population et d'autre part qu'il n'existe aucune règlementation concernant les interactions en présentielle, les recommandations portant sur ces deux types de CDCM peuvent ainsi être pertinentes et s'appliquer à l'ensemble des juridictions.

Établir des repères éthiques

Une fois le regard porté sur l'éventail des pratiques de CDCM et d'avoir formulés des recommandations à l'égard de l'hétérorégulation et des « règles du jeu » pour des pratiques acceptables (Partie II), il convient de réaliser que, sans une implication et un engagement de l'industrie, il est difficile d'en arriver à induire de meilleures pratiques marketing. L'intérêt de la complémentarité entre l'hétérorégulation et l'autorégulation est que l'ensemble des acteurs peuvent y trouver leur compte : pour les agences règlementaires, cela permet une meilleure atteinte et conformité avec leurs objectifs populationnels, et pour l'industrie, cela lui permet de conserver une marge de manœuvre et une flexibilité en évitant de se voir réguler par des règles du jeu qui minent trop leur modèle d'affaires.

Dès lors, dans la Partie III, l'accent est mis sur l'autorégulation tout en s'intéressant directement à ceux et celles qui sont confrontés à ces enjeux et dilemmes éthiques dans leur pratique quotidienne, c'est-à-dire aux professionnels et spécialistes en marketing pharmaceutique. Ainsi, l'audience particulière (et les objets d'étude) de la section III s'est déplacée des régulateurs aux employés eux-mêmes et, plus largement, aux entreprises qui les embauchent. Le Chapitre 6 s'est ainsi attelé à faire l'analyse des considérations saillantes des études de cas réels, sur la base des

théories morales classiques : le conséquentialisme, le déontologisme, l'éthique de la vertu et le contrat social. Ce tour d'horizon des fondements moraux balisant la conduite et les considérations éthiques majeures a été réalisé d'une manière accessible et détaillée de sorte que des non-experts en éthique, mais spécialistes du marketing pharmaceutique, puissent comprendre les implications de leur pratique quotidienne.

Un ensemble de repères éthiques ont été dégagés grâce à la quadruple lentille des théories morales ayant tour à tour été appelées à fournir un éclairage sur les pratiques de CDCM et les considérations saillantes qui devraient les guider. Cette idée d'une éthique des pratiques marketing (et plus spécifiquement des CDCM) ne s'arrête pas là où la réglementation gouvernementale se termine et toutes les pratiques ne sont pas égales par rapport aux arguments moraux utilisés pour justifier son acceptabilité, c'est-à-dire la fourniture d'informations significatives et efficaces sur les consommateurs qui favorisent l'éducation et permettent aux consommateurs de faire des choix éclairés et autonomes. La mise en place de structures et de guides pour aligner les pratiques commerciales aux impératifs sociaux permet de donner les moyens aux compagnies (et à leurs employés) de mieux reconnaître leur agentivité et d'agir d'une manière qui répond à leur responsabilité sociale, et donc au contrat social.

Ainsi, pour guider le comportement et les pratiques des « joueurs » (c'est-à-dire, de ceux au sein de l'industrie), a été proposé l'établissement d'un minimum éthique (*moral bottom line*) sous la forme d'impératifs et d'un engagement éthique. L'objectif n'est pas tant de leur faire porter un fardeau indu en termes de responsabilité, mais plutôt de reconnaître leur rôle dans la relation de soin et conséquemment leur part à jouer dans le partage de la responsabilité; ils font partie à la fois du problème que de la solution. Le dernier impératif de l'engagement met justement l'accent sur le côté inclusif par rapport à la relation de soin : l'individu (l'employé marketing) qui s'y conforme serait alors reconnu comme étant digne de confiance et une source d'information fiable faisant partie intégrale de l'amélioration de la santé et du bien-être social.

Bien entendu, un tel engagement ne peut être suivi, si l'entreprise pour laquelle les employés travaillent ne s'engage pas elle aussi à reconnaître son rôle et ses responsabilités. Elle doit donc donner les moyens et la marge de manœuvre à ses employés pour arriver à concilier les

impératifs de profitabilité et sociétaux, de même qu'à résoudre d'une manière authentique les dilemmes éthiques.

Retombées de la thèse

Plus généralement, les repères éthiques établis au Chapitre 6 – formulés sous une forme engageante et applicable à tous les contextes juridictionnels indépendamment des pratiques autorisées par l'hétérorégulation – peuvent servir de base à l'établissement des standards pour l'ensemble de l'industrie. Ainsi, alors que l'International Federation of Pharmaceutical Manufacturers & Associations (2015) n'a pas inclus dans son code d'éthique des dispositions sur les CDCM dû à la variabilité juridictionnelle qui prévaut quant à la permissivité des divers dispositifs marketing rejoignant directement les consommateurs, les repères éthiques dégagés dans le Chapitre 6 pourraient facilement servir de base à un cadre international, et ainsi permettre une harmonisation des repères éthiques internationaux. Ceci est une contribution importante de cette thèse pour de futurs développements, à l'échelle internationale, de l'encadrement éthique des CDCM.

En plus de s'intéresser à l'éthique du marketing pharmaceutique, cette thèse s'est également penchée sur les outils nécessaires pour soutenir le regard bioéthique dans son appréciation de la complexité des enjeux entourant l'industrie pharmaceutique. Une exploration des propositions existantes de bioéthique pharmaceutique a donc été réalisée et la portée de ces propositions a été étendue à l'ensemble des activités de l'industrie, incluant le marketing. Cette autre contribution à la littérature permet d'offrir une lentille spécifique, à la fois théorique et opérationnelle, pour comprendre et résoudre l'ensemble des problèmes éthiques au sein de l'industrie pharmaceutique. Dès lors, en guise de retour sur les outils de la bioéthique et sur l'importance d'un regard normatif qui inclut les dimensions commerciales, le Chapitre 7 a permis de formuler l'énonciation d'une bioéthique habile à concilier et balancer des enjeux éthiques qui pourraient paraître, de prime abord, quelque peu à l'extérieur de son épistème. Il a donc été proposé d'ajouter une double orientation au principe classique de bioéthique, l'une sociétale et l'autre commerciale. Cet ajout est en phase avec la démonstration de la nécessité d'inclure des outils conceptuels permettant d'élargir l'appréciation des considérations ayant une

valeur morale en bioéthique sur la base de l'analyse de l'apport de la responsabilité sociale des entreprises (RSE) au champ de la bioéthique (Chapitre 2).

L'ébauche de la bioéthique pharmaceutique proposée permet d'ajouter une dimension supplémentaire aux approches théoriques et au corpus existant en bioéthique. Un tel cadre d'analyse a l'avantage d'élargir les approches en éthique clinique en allant au-delà de la relation médecin-patient (ou, en éthique de la recherche, la relation investigateur-participant), en prenant en considération, lors de l'analyse éthique et de la prise de décision, les implications des dimensions commerciales au sein des questions éthiques. Cet éclairage permet d'appréhender une réalité complexe et dynamique et aider à porter un jugement normatif alliant les considérations *sine qua non* tant de l'industrie que de la société. Les considérations bioéthiques pourront dès lors être intégrées au sein de l'industrie tout autant que seront considérés les dilemmes éthiques vécus par l'industrie en bioéthique. Cette double orientation aux principes et considérations bioéthiques permet d'appréhender d'une manière plus outillée les dilemmes éthiques survenant lorsque des impératifs de profit croisent le chemin de la santé humaine. Bien que l'accent ait été mis sur le secteur pharmaceutique, le modèle pourrait tout à fait être appliqué dans d'autres secteurs comme les systèmes d'assurances santé, les tests de dépistage génétique, etc. Les applications sont nombreuses, dès lors qu'entrent en considération des intérêts commerciaux.

Recherches futures

À l'aboutissement de cette thèse, semble impérative la nécessité d'une validation empirique tant des repères éthiques établis que de la pertinence et faisabilité de la bioéthique pharmaceutique. Pour ce faire deux grands chantiers devraient être mis de l'avant : 1) une enquête internationale sur les repères éthiques qui devraient guider l'hétérorégulation et l'autorégulation des pratiques de marketing direct aux consommateurs; et 2) une étude empirique explorant la faisabilité et l'efficacité de déployer au sein des entreprises un cadre de bioéthique pharmaceutique permettant de soutenir les employés.

Sur la base des repères éthiques et des recommandations dégagés par cette thèse, il serait opportun de tenir une discussion ouverte, impliquant à la fois les décideurs politiques et les représentants de l'industrie, sur l'état actuel et sur l'évolution des pratiques de CDCM en recherchant des moyens efficaces pour mieux les réguler. Les objectifs d'une telle discussion seraient de: 1) brosser le portrait international de l'environnement réglementaire actuel, pour voir si, pourquoi et comment les pays et les entreprises régulent les diverses formes de CDCM; 2) anticiper les développements futurs des CDCM et leur impact sur les consommateurs et la société; 3) déterminer quelles sont les considérations éthiques et régulatoires prioritaires; 4) déterminer les formes les plus prometteuses d'hétérorégulation et d'autorégulation, capables de surveiller et guider efficacement les pratiques; 5) aboutir à un consensus entre les décideurs politiques et les représentants de l'industrie sur l'établissement d'un programme de règlementation et convenir d'un agenda pour sa mise en place.

Les visions divergentes à plusieurs égards constituent une occasion de discussion et de débat entre les parties prenantes des gouvernements et de l'industrie venant de différentes juridictions afin de mieux comprendre les sources de leurs désaccords et la justification des règlementations nationales actuelles. Une telle conversation mondiale cherchant des solutions mutuellement avantageuses n'a jamais encore eu lieu alors qu'elle saurait permettre une meilleure compréhension, une entente et une harmonisation de la régulation internationale pouvant s'appliquer aux particularités de chaque juridiction, ainsi que de définir les termes et les repères éthiques qui devraient guider les pratiques de CDCM.

Cette exploration du chevauchement entre la bioéthique et les considérations commerciales ouvre tout un nouveau champ d'études et à des contextes de pratique de la bioéthique directement au sein des entreprises. Une critique possible porte évidemment sur le degré d'authenticité d'une telle démarche et à quel point la bioéthique pharmaceutique peut être instrumentalisée au profit des entreprises. Cette considération est déjà présente en ce qui concerne la RSE et a été abordée précédemment, mais ne devrait pas amoindrir l'intérêt d'éprouver dans le contexte réel la faisabilité et l'efficacité de cette lentille à guider de l'intérieur des pratiques de l'industrie. Il convient par conséquent de mener un ensemble d'études

empiriques au sein des entreprises, ainsi que de dresser un agenda de recherche pour parvenir à déployer la bioéthique pharmaceutique au sein de l'industrie.

Qui plus est, en vue d'offrir des arguments supplémentaires pour convaincre le secteur de s'engager dans la conformité éthique de leurs pratiques marketing, une évaluation pharmacoéconomique permettrait d'apprécier l'impact commercial réel de l'engagement moral des entreprises. *A priori* potentiellement négatif, considérant le rôle et l'importance que joue le marketing à stimuler la vente des médicaments, l'impact peut au contraire s'avérer nul ou même avantageux sur le plan de la profitabilité des compagnies. Cela peut s'avérer un grand champ de recherche pour la pharmacoéconomie qui intègrerait la dimension éthique, non pas comme une simple externalité, mais comme facteur-clé de succès du secteur.

Remarque finale

L'un des objectifs de cette thèse était d'en arriver à remettre l'individu au centre des processus réflexifs et décisionnels. Il convient de reconnaître la complémentarité entre l'hétérorégulation et l'autorégulation, mais surtout la nécessité d'outiller et de soutenir les individus (ce qui demeure une des forces de la bioéthique) comme l'avenue la plus prometteuse d'induire de réels changements en termes éthiques et sociétaux. Considérant que les problématiques éthiques entourant les médicaments sont souvent générées au sein des entreprises, il convient d'induire un changement permettant d'enchâsser la conciliation des profits et visées pro-sociales comme nécessité morale et fondement éthique des pratiques de l'industrie. Dès lors, tout autant que l'objectif bienfaisant putatif des CDCM est l'autonomisation des individus, n'est-il pas logique de vouloir appliquer la même « médecine » aux marketeurs? Les soutenir à faire usage de la bioéthique pharmaceutique comporte justement une volonté visant à les autonomiser. En effet, la grande majorité des employés ont à cœur la santé des populations et de faire en sorte que leur entreprise fasse une différence. Au lieu de simplement les critiquer, il convient de les guider dans cette démarche tout autant qu'il est nécessaire de s'assurer que leur entreprise leur donne les moyens et l'espace d'agir d'une façon conforme aux doubles attentes que sont la profitabilité de leur entreprise et la santé des populations.

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Annexe 1 : Preparing for the Arrival of *Pink Viagra*

Bélisle-Pipon, J.-C. et Williams-Jones, B. (2016). Preparing for the arrival of « pink Viagra »: strengthening Canadian direct-to-consumer information regulations. *Canadian Medical Association Journal*, *188*(5), 319-320. doi:10.1503/cmaj.150705

Do you remember the ad with a cartoon elephant lying in bed between a man and a woman, implying that there was a huge problem in the bedroom? This ad was the beginning of a direct-to-consumer information (DTCI) campaign about erectile dysfunction (ED). Called *40over40*, the campaign was sponsored by Eli Lilly, manufacturer of Cialis (Tadalafil).

But the popular media focus on male sexual performance has changed, following the FDA's recent announcement of the approval of flibanserin (Addyi) for the treatment of acquired, generalized hypoactive sexual desire disorder (HSDD) in premenopausal women (FDA, 2015a). Often referred to as "Viagra for women" or "Pink Viagra", flibanserin was twice refused by the FDA in the past 5 years (Segal, 2015); as a result, in 2011, the initial producer, Boehringer Ingelheim, transferred the rights to flibanserin to Sprout Pharmaceuticals, which were then recently transferred to the Canadian company Valeant Pharmaceuticals.

We can expect that an application to Health Canada for marketing authorization will follow close on the heels of the FDA approval. If approved in Canada, it will of course not be possible for Valeant to promote flibanserin using direct-to-consumer advertisements (DTCA), which are permitted in the US but prohibited under Canadian law. However, it is legal for a company to "inform" consumers about the drug through direct-to-consumer information (DTCI) campaigns. These campaigns, such as the one by Eli Lilly, aim at "creating general disease awareness (e.g., about symptoms and associated health risks) and encouraging patients to ask their doctor about whether they might have the medical condition." (Bélisle-Pipon et Williams-Jones, 2015a). For example, Sprout Pharmaceutical cited evidence that between 7 and 33% of women suffer from HSDD (Sprout Pharmaceuticals, 2015), so the potential market is huge. We can thus expect flibanserin to be the subject of a DTCI campaign in Canada, most likely with messages similar to those offered by Eli Lilly in the case of tadalafil, that it is *imperative* that women be sensitized

to this major public health problem, one that can have a significant impact on the quality of life of women… and their partners. Furthermore, the development of competing products by manufacturers such as Palatin Technologies, show that there is interest in producing drugs to "treat" women's libidos, a market that has been estimated to be worth $1.5 to 2 billion (Dearden, 2015).

What are the responsibilities of Canadian health regulators and advertising standards authorities? Eli Lilly's *40over40* DTCI campaign was accredited by Advertising Standards Canada (ASC), a certifying agency mandated by Health Canada to assess content and compliance of the material voluntarily submitted by sponsors. But while judged compliant by ASC, the campaign was rather more "promotional" than "informative" and arguably indistinguishable from prohibited DTCA (Bélisle-Pipon et Williams-Jones, 2015b). Flaws in existing Canadian regulations that permitted tadalafil to be marketed in this way still exist and can be exploited by Valeant.

The *40over40* campaign strongly implied that 40% of men over 40 years old suffer from ED, a rather good marketing claim but one not well-supported by strong scientific evidence (including on the campaign's website) (Bélisle-Pipon et Williams-Jones, 2015a). In their campaign to achieve FDA approval of flibanserin, Sprout argued that HSDD is a prevalent condition affecting as many as one in three women in the United States (Sprout Pharmaceuticals, 2015). This, too, is a very convincing marketing claim, but reliable and independent scientific sources show that only about *one in ten* women experience distress and thus suffer from HSDD (Leiblum, Koochaki, Rodenberg, Barton et Rosen, 2006; Moynihan, 2014). It will be interesting to see how the quality of evidence – both with regards to the severity and incidence of the condition – is treated in any DTCI campaign in Canada.

Flibanserin is the only drug so far approved to treat HSDD. DTCI efforts are not allowed to promote one drug over others, yet it would be difficult to ensure that DTCI activities do not present only a single product in this case. But even in the case of tidalafil, where alternative treatments existed, information was presented in such a way as to suggest that tidalafil represented a "gold standard", and other non-drug alternatives where either cast in a more

negative light or not mentioned at all (e.g., no discussion of psychosocial interventions or counselling, although evidence may show that effective treatment requires a combination of approaches (Berry, 2013)). It will also be interesting to see how Valeant deals with ASC's requirement that "no element can directly or indirectly promote the sale of a drug" (Advertising Standards Canada, 2011).

The social context in which drug information is presented is important to consider. Sprout's pre-approval campaign implied that sexism may be at play in the "under" treatment of HSDD (i.e., specifically pointing out that there are many drugs to treat ED in men but no treatment for the female equivalent) (Moynihan, 2014; Segal, 2015). This should make alarm bells ring. Any DTCI campaign should meet standards by being as neutral as possible and unbiased by a misplaced motive of responding to gender inequity. Bias is introduced if emotive campaigns that are not linked to strong evidence underpin the provision of information. What about asking the more pertinent question of whether the existing evidence can tell us whether the condition really exists or whether drugs are really the only response to a "dysfunctional" level of sexual desire?

To respect the spirit of Canadian DTCI regulations, an HSDD campaign should not promote a specific treatment but only neutrally inform the public about symptoms, patient health and possible solutions. But flaws in existing regulations mean that companies can "play by the rules" and still deploy DTCI campaigns that are in fact promotional, and thus DTCA in everything but name, as illustrated by the example of tidalafil (Bélisle-Pipon et Williams-Jones, 2015b). There is a window of opportunity for Health Canada to review its current rules and procedures, recognise that the problems posed by DTCI are essentially the same as for prohibited DTCA, and to move to tighten regulations. A first step is the long overdue modernization and clarification of the document "The Distinction Between Advertising and Other Activities", which currently serves as the main reference point for DTCI regulation. The rules governing information and promotional activities must be clear to sponsors (and to the public), and supported by a truly dissuasive sanction regime. Health Canada must assume its responsibilities for controlling drug promotion, responsibilities that are currently delegated to ASC, a non-governmental organization that relies on corporate self-regulation. And this means that the

federal government must ensure that Health Canada has the necessary time and resources to protect the public from "informational" messages that are essentially another form of drug advertising.

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