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A Prescription for Pharma

Social Media Reality Check

Human-generated content analysis allows an understanding of user engagement in web-based healthcare communities. This study uses the human-generated method to unpack how patient-consumers and other industry actors connect in online forums about oral contraceptives. Collecting data and observing public discourse on voluntarily consumed medicine rather than survival drugs allows for the exploration of normative and behavioral issues of consumers engaged in risky prescription drug use. This research can aid the pharmaceutical industry in understanding how informal social media forums influence public opinion about the safety and benefits of oral contraceptive drugs.

Katherine Relle
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Executive Summary

The U.S. Food and Drug Administration (FDA) have issued no formal policies, laws, or regulations governing the pharmaceutical industry's use of social media for product marketing and health information services. The lack of FDA regulation, coupled with the fast-paced social media environment, has left the pharmaceutical industry cautious in establishing social media strategies. However, social media research offers insight about the public's perception, degree of trust, and reliance on pharmaceutical companies to provide studies about a drug's benefits and other health-related information.

This study uses human-generated content analysis to understand user engagement in web-based healthcare communities. The research unpacks how people connect in online forums about oral contraceptives. Collecting data and observing public discourse on voluntarily consumed medicine rather than survival drugs allows for the exploration of normative and behavioral issues of consumers who are or have been engaged in risky prescription drug use. These findings can aid the pharmaceutical industry in understanding how informal social media forums influence public opinion about the safety and benefits of oral contraceptive use.

While traditional content analysis overcomes subjective flaws by remaining methodologically impartial, nuanced content may be omitted in some cases. Human Digital's human-generated technique counteracts this methodological flaw by employing a human analysis of online content rather than the use of programmed software that cannot account for syntactic peculiarities in sarcasm, irony, acronyms, and other contextual material. By employing the human-generated method to study how informal social media forums modulate public opinion on risky prescription drug use, findings will be of value to pharmaceutical industry stakeholders interested in improving their understanding of patient-consumers in the four core areas of risk communication, personal profiling, education, and sentiment analyses.

Section One: Research Motivations

❖ Historical Background

In 2008, social scientists Heather Hartley and Cynthia-Lou Coleman published research findings on Direct-to-Consumer (DTC) pharmaceutical advertising in *health: An Interdisciplinary Journal for the Social Study of Health, Illness and Medicine*.¹ Hartley and Coleman's study follows the 1997 shift in regulatory policy established by the U.S. Food and Drug Administration (FDA). Prior to 1997, the FDA ruled that full disclosure of prescription drug risks was required in DTC pharmaceutical advertising. The policy discouraged drug companies' use of expensive advertising in limited commercial space. In 1997, the FDA's *Draft Guidelines for Industry: Consumer-Directed Broadcast* ruled otherwise. Risk requirements in DTC advertising could be satisfied by reference to alternative sources of information, such as websites.² By loosening the regulatory environment, the FDA initiated a sudden increase in televised DTC pharmaceutical advertising.

Hartley and Coleman's paper discusses the effect of the 1997 ruling. They conclude that the regulation allowed corporate sellers more media prominence, leaving DTC critics with little media representation. This finding suggests a skew in "countervailing powers" toward the pharmaceutical industry, colloquially called *big pharma*, giving the industry disproportionate control over its consumer base.³ Effectively, the 1997 regulation contributed to industry-stakeholder empowerment instead of promoting a more egalitarian relationship between the big pharma and pharmaceutical consumers.

❖ Contemporary Backdrop

Today, social media give patients and muted DTC critics a chance to be heard. Social media exist in many forms. Blogs, social networking sites, collaborative projects, content communities, and virtual social worlds are all social media applications continuing to increase in popularity.⁴ According to a 2010 study by the Nielsen Company, "The U.S. had the largest number of social media users, totaling more than 140 million unique users in December 2009 alone."⁵ This large statistic illustrates the reason many U.S. businesses have been driven to use social media for marketing products, gathering information, and promoting brands in the current media climate.

¹ Hartley, Heather and Cynthia-Lou Coleman. "News Media Coverage of Direct-to-Consumer Pharmaceutical Advertising: Implications for Countervailing Powers Theory." *health: An Interdisciplinary Journal for the Social Study of Health, Illness and Medicine* 12.1 (2007). Print.

² Hartley and Coleman, p. 109.

³ Countervailing powers theory is the idea that modern economies give a great deal of power to large corporations; thus, countervailing powers arise in the form of unions, citizens' organizations, etc. to offset business' excessive advantages. From Hartley and Coleman, p. 107.

⁴ Liu, Kassity. "FDA and Social Media: The Impact of Social Media on Prescription Drug Advertising" *Harvard Journal of Law & Technology*. Jolt Digest, 17 April 2012. Web. 9 June 2012. <<http://jolt.law.harvard.edu/digest/digest-comment/fda-and-social-media-the-impact-of-social-media-on-prescription-drug-advertisin>>

⁵ The Nielson Company. "Social Networking Activity per Country" *Nielson*. Nielson, 2009. Web. 10 June 2012. <<http://www.nielson.com/us/en.html>>

Activity in web-based health forums is particularly on the rise. In a 2009 study by the Pew Research Center's Internet & American Life Project, 61 percent of American adults searched online for healthcare information, and of that group, 41 percent had "read someone else's commentary or experience about health or medical issues on an online news group, website, or blog."⁶ Similarly, the National Research Corporation found that one in every five Americans used social media as a source of healthcare information, and of survey-respondents, 25 percent were "likely" or "very likely" to be influenced by healthcare information on social media sites.⁷ These findings suggest that patient-consumers are increasingly engaged in an online dialogue. As a result, big pharma companies are casting their business plans online, but the FDA are yet to publish formal regulatory guidelines for an industry-wide social media policy.

Instead, guidance is in the form of a 2011 preliminary document, *Draft Guidance: Responding to Unsolicited Requests for Off-Label Information about Prescription Drugs and Medical Devices*.⁸ The document discusses how the pharmaceutical industry may legally respond to unsolicited questions⁹ about off-label drug use on social media sites.¹⁰ The document is criticized for reiterating past FDA policy, and for being too heavily comprised of negative regulation rather than positive policy suggestions for the advancement of social media marketing in the industry.¹¹

The absence of formal regulatory guidance and market precedence alongside abstract power struggles between the industry and its consumers burdens prescription drug companies. Big pharma waits for active governance, but pharmaceutical companies cannot avoid the use of social media in the meantime; "consumers will be talking about [drug companies] whether [they] are [using social media] or not."¹² Social media engagement is inevitable for the pharmaceutical industry. Thus, this research aims to provide an inductive, critical analysis to aid big pharma companies engaging in self-governance to understand the online presence of prescription drug consumers. This will help companies take proactive measures to advance their online presences.

⁶ Pew Research Center. "Press Release: 61% of American adults look online for health information" *Pew Internet & American Life Project*. Pew Research Center, 11 June 2009. Web. 15 June 2012. <<http://www.pewinternet.org/Press-Releases/2009/The-Social-Life-of-Health-Information.aspx>>

⁷ National Research Corporation in Liu, Kassity.

⁸ U.S. Food and Drug Administration. "Guidance for Industry Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices" *U.S. Food and Drug Administration*. n.p., December 2011. Web. 20 March 2012. <<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM285145.pdf>>

⁹ unsolicited=

¹⁰ The following is an excerpt from the 2011 FDA document, illustrating its vague diction: "FDA has long taken the position that firms can respond to unsolicited requests for information about FDA-regulated medical products by providing truthful, balanced, non-misleading, and non-promotional scientific or medical information that is responsive to the specific request, even if responding to the request requires a firm to provide information on unapproved or un-cleared indications or conditions of use. If responses to unsolicited requests fall within these parameters, FDA has not expected those responses to meet regulatory requirements for promotional labelling or advertising and has not considered these responses as evidence of intended use. This draft guidance sets forth FDA's current thinking on this topic, consistent with the Agency's past policy statements about responding to unsolicited requests. Regardless of whether the initial unsolicited request for off-label information was made in a non-public or public forum, a firm that chooses to respond should provide the final response containing the requested off-label information about its product only to the specific individual who requested the information."

¹¹ Tambini, Damian and Liz Forgan. *Content Regulation: A New Settlement*. London: IPPR, 2001. Print.

¹² Folkens, Dave. "Why Social Media is a Must in Pharma Marketing" *Top Rank Online Marketing Blog*. Top Rank, n.d. Web. 10 June 2012. <<http://www.toprankblog.com/2011/01/social-media-marketing-pharma/>>

Section Two: Research Outline

❖ Research Question

This study, instigated by the lack of concrete social media guidance for the pharmaceutical industry, seeks to investigate the potential for big pharma's social media management by employing an inductive content analysis to answer the following questions: Should big pharma engage in web-based discussions on social media websites? If so, how can the application of a disciplined, inductive approach to social media data improve big pharma's understanding of patient-consumers? What are the impacts of this study from both the marketing and product development standpoints?

❖ Analytical Criteria

In an article published by *The Harvard Journal of Law & Technology*, "FDA and Social Media: The Impact of Social Media on Prescription Drug Advertising", four hypothetical criteria are suggested for rationalizing why pharmaceutical companies should engage with social media.¹³ These criteria are the following:

1. *Risk Communication*: If questions or comments posted in online forums are left unanswered "companies may lose control over their promotional messages and incur ... negative publicity. Third party bloggers ... can easily use social media tools to respond to online promotional material ... [and] when this information is misleading or inaccurate, the firm ... may find itself mired in legal and media troubles."¹⁴
2. *Profiling*: "By engaging in social media, firms can gain insight about new products, develop more targeted marketing practices, and better understand market needs."¹⁵
3. *Education*: "Companies can use social media to advance public health and provide benefits to their patients and the medical community."¹⁶
4. *Sentiment*: "Companies can learn from one another's experiences and collaboratively develop best practices for the industry."¹⁷

Accordingly, this paper hypothesizes, first, that online forums will contain a high degree of user-generated risk communication. Postings will serve as counter-power messages to DTC pharmaceutical advertisements lacking overt statements of risk.¹⁸ Second, online forums will be useful for understanding the prescription drug user base. Third, online forums will serve an educational purpose through an interactive question and answer format. Lastly, online forums will reflect a range of positive and negative sentiment toward the industry. If these hypotheses are correct, the utility of social media for the pharmaceutical industry matches the value proposed by *The Harvard Journal of Law & Technology*, providing grounds for big pharma's formal presence in online health forums as well as insight into consumer markets.

¹³ Liu, Kassity.

¹⁴ Liu, Kassity.

¹⁵ Liu, Kassity.

¹⁶ Liu, Kassity.

¹⁷ Liu, Kassity.

¹⁸ Castells, Manuel. "Communication, Power and Counter-power in the Network Society." *International Journal of Communication* 1.1 (2007). Print.

❖ Method: Case Study

This research project employs human-generated content analysis to understand engagement in online healthcare communities. The project studies how social media users connect through three online forums—Experience Project, Topix, and Gather—on the topic of oral contraceptives. Research on oral contraceptives rather than other prescription drugs was chosen as an illustrative case study because many patients take oral contraceptives by choice rather than to overcome severe illness.¹⁹ The nature of this personal decision generates diverse online discussion about the normative issues surrounding oral contraceptive drug products from a consumer standpoint.

❖ Data Collection

The three forums—Experience Project, Topix, and Gather—were chosen in a random Google Search to provide variance to the dataset and help determine the prevalence of particular content. The commonality between the three health forums is that each contains “birth control pill” labeled discussion boards.²⁰ Justification for this method is that online audiences of patient-consumers researching oral contraceptives are highly likely to visit popular Google Search generated sites, as observed by the researcher’s experience working in Federal Government Affairs at a global pharmaceutical company. Consent was requested by the forum moderators at each site for investigation into the public posts.²¹

The research looked at 100 percent of the first 200 (most recent) posts in each oral contraceptive forum despite the post length. A total of 600 posts were analyzed. It was largely the case that posts were comprised of at least two sentences. Nonsensical and off-topic posts that added no qualitative advantage to the research were eliminated from the dataset. The number 200 was generated because it is the total number of birth control pill-related posts in the forum with the least amount of relevant posts, Experience Project. The numerical standardization served to ease data cross-analysis. Precise criteria may be found in Appendix 2.

❖ Coding & Inter-coder Reliability

For each of the 600 total posts, coding was performed on ten variables, as follows: Date, Identity, Age, Gender, Brand, Format, Nature, Emotion, Moral, and Political. Complete descriptions of the coding frame may be found in Appendix 2. By employing content analysis, the relationship between, for example, identity (i.e., a patient-consumer) and risk concern (i.e., serious concern) can be numerically interpreted in an SPSS cross-tabulation. Content analysis, therefore, simplifies data comparison and provides an empirical dataset available for further research.

To validate objectivity, inter-coder reliability was established by two pilot tests. Results from these tests may be found in Appendices 1 and 2. To generate inter-coder reliability, an outside party was given the first draft code. Both he and the researcher coded the first ten posts in the

¹⁹ Iversen, Leslie. *Drugs: A Very Short Introduction*. New York: Oxford University Press Inc., 2001. Print.

²⁰ The colloquial name ‘birth control pill’ was used instead of ‘oral contraceptive’ to account for the greater audience appeal.

²¹ Names and detailed descriptions are left out of the analyses to preserve posters’ anonymousness by the particular request of Experience Project moderators.

dataset and responses were compared. Ones were assigned to like answers while zeros were assigned to different answers. Totals were calculated for each variable. The first draft code established 74 percent reliability. While 70 percent reliability is minimally acceptable, the code was re-worked by both coders. A second inter-coder reliability test was performed on the revised code using a new co-coder to preserve impartiality. The test methods were identical to those conducted in the first pilot test. The second test generated 98 percent reliability. The revised code was used for data gathering.

❖ Limitations

Content analysis remains a challenge to perform in the online environment as it stems from journalistic roots and has been traditionally employed for research into clearly defined coding frames (i.e., newspaper articles).²² Noticeably, it is difficult to maintain a definitive coding unit in online forums where content is layered and scattered.²³ This limitation is acknowledged by the researcher.

The researcher also anticipated the difficulty in computer-generated analyses of nuanced content. Therefore, a human-generated content analysis was used because computer-generated research cannot account for syntactic peculiarities such as sarcasm, irony, acronyms, and other contextual material with which human beings are more familiar. Regardless, human-generated content analysis will always retain some degree of subjectivity. This limitation is also acknowledged.

Section Three: Findings and Discussion

❖ Findings: Risk Communication

Across all forums, an ordinal code was applied for the risk concern variable. The variable was comprised of the following options: 1) no concern for health risk, 2) mild concern for health risk, and 3) serious concern for health risk. Of the 600 analyzed forum posts, 53 percent identified no concern for health risks and 47 percent identified either mild or serious concern for health risks. Of the posts expressing either mild or serious risk concerns, 61 percent communicated overt negative statements against the use of oral contraceptives. This outcome suggests that a majority of those posts expressing either mild or serious concerns for health risks linked to the use of oral contraceptives find risk to be more concerning than the alternative potential positive aspects of the product.

In a trend analysis with an explanatory variable defined by date and a response variable defined by nature of risk concern, an SPSS output showed that 43 percent of the analyzed posts posted in or after 2011 expressed mild or serious risk concern. This figure is compared with the posts that were posted between 2005 and 2010, where 51 percent of the analyzed posts expressed mild or serious risk concern. These close figures are significant at the one percent significance level and validated by a high Pearson chi-square test statistic of 11.295 (at two degrees of freedom) with a p-value of 0.004 ($p < 0.01$), where zero cells have expected counts less than five. This test shows that there is a notable association between the response and explanatory variables, based on the

²² Krippendorff, K. *History*. In *Content Analysis*. 2nd ed. London: Sage, 2004, p. 3. Print.

²³ Krippendorff, K., p. 17.

population of analyzed posts. The test statistic suggests that there is an increase in use of social media for expressing risk concern over time, as the statistic defining the shorter time frame almost equates the statistic defining the longer one. Refer to Appendix 3 for the complete SPSS output.

❖ Findings: Personal Profiling

Across all forums, no posts were made before 2005. The fact that 52 percent of the posts were made since 2011 illustrates implications mentioned in the Nielson Company's statement about the mass increase in U.S. social media use, which is iterated in Chapter 1. Of these posts, 45 percent of posters identified themselves to be patient-consumers and seven percent of posters were speaking on behalf of patient-consumers. Therefore, 52 percent of posters had some direct or indirect personal experience with oral contraceptives. There were (unsurprisingly) no self-identified industry stakeholder posters, and only one percent of the posts were made by self-identified healthcare providers. Forty-six percent of posters did not provide an identity. These statistics suggest that, of those who self-identified, a majority of forum posters came in either direct or indirect contact with the drugs.

Additionally, posters seemed to provide sparse information about their personal identities (perhaps, due to the sensitive nature of the health-related topic). Eighty-six percent of posters did not reveal their ages and 27 percent of posters gave no inclination of their genders. Even though no larger percentage than 27 percent explicitly stated their genders, it remained fairly obvious what genders of posters were due to the content of the posts relative to the utility of oral contraceptives. Of those posts supplying adequate information to determine gender, 62 percent were made by women posters and 11 percent were made by male posters.

Typically, male posters expressed concerns or comments about their partners' use of oral contraceptives. Otherwise, male posters expressed general concerns or comments about either political or moral issues surrounding oral contraceptives. In fact, self-identified male posters made up 31 percent of all posts with religious content and 20 percent of all posts with political content. This statistic is interesting considering there were (not unexpectedly) fewer self-identified male posters in the overall dataset than female posters, yet these statistics almost match those percentage values yielded by female posters in the equivalent cross-tabulations. Another point of interest is that in 100 percent of the religious content identifying a specific religion, the reference was to Catholicism. The political content contained references to a wider array of parties than was the case with the variance expressed in the religious references. Refer to Appendix 4 for the complete SPSS output.

❖ Findings: Education

Across all forums, 27 percent of the posted content was formatted as a request for information. Of this format, 63 percent of the posts also communicated either mild or serious concern about the risk of oral contraceptive use, with 25 percent of posts expressing negative sentiments about the drugs and 5 percent of posts expressing positive sentiments (the remaining content in the format variable gave mixed sentiment). These statistics suggest that a solid quarter of all content posters sought information about oral contraceptives out of concern for their health. Positively

sensitized content usually asked about brand comparison, especially for off-label drug usage (i.e., using oral contraceptives for acne) while negatively sensitized content provoked the online public sphere by asking whether other patient-consumers experienced similar adverse reactions to particular brands of drugs.

The SPSS output shows that of those who did not request information (the remaining percentage in the format variable), 27 percent responded to questions and 21 percent commented about personal experiences. These percentages total 75 percent of all posters who engaged in some sort of interactive dialogue. The remaining 25 percent of posts were either general comments or retail advertisements. This data supports the suggestion that “many patients ... use social media to share and obtain information about pharmaceutical products, [so] drug manufacturers can advance public health by ensuring that reliable and accurate information about their products is disseminated online.”²⁴

For instance, retail advertisements (i.e., generated by online pharmacies rather than the industry itself) presented bias in favor of particular brand drugs in their explicit online advertisements, whereas patient-consumers presented more skeptical views in their accounts of unpleasant and dangerous side effects of brand drugs relative to particular patient history. These findings imply that if drug manufacturers could act as responsible modulators by presenting clear and disinterested safety information about their products (i.e., via a social media ombudsman role), the industry would gain patient-consumer trust—a clear benefit for brand identity. Refer to Appendix 5 for the complete SPSS output.

❖ Findings: Sentiment

Across all forums, only 17 percent of the posts contained content praising oral contraceptives. Forty-eight percent of the total content held mixed sentiment and 35 percent of the total content was explicitly negative toward oral contraceptives. These statistics suggest there to be room for a countervailing industry voice, at some level, despite the negative connotation of having the industry voice present.

Within the negatively sensitized content, 42 percent of the content referenced some brand name oral contraceptive drug, one percent referenced religious issues, and six percent referenced political issues. These findings show that more people were provoked to post negative sentiments about specific manufacturer’s products than about political and religious issues surrounding oral contraceptives more generally. These negative online sentiments foreshadow the growth of a lop-sided public sphere. A lop-sided public sphere is disadvantageous to the industry and the integrity of the normative public sphere. Refer to Appendix 6 for the complete SPSS output.

❖ Discussion

The data proves that engaging in social media is a necessary endeavor for the pharmaceutical industry. This conclusion is proposed based on the aforementioned analytical criteria of risk communication, personal profiling, education, and sentiment. Content analysis permits claims to

²⁴ Liu, Kassity.

be made about a range of representations because cross-analyses provide objective statistical conclusions that validate suggestions for industry improvements, which are outlined as follows.

First, nearly half (47 percent) of online posts involved risk messages. Online risk messaging threatens company branding because informal social media messages may be inaccurate when not vetted by industry experts. Big pharma needs to engage with social media to protect company brands. **Second**, even though patient-consumers were reluctant to provide much personal information (i.e., gender or age), the information that was provided often elicited decipherable traits due to the nature of the posts. Personal information in these posts provided interesting characteristics based on legitimate profiling assumptions, which could help inform relevant marketing practices concerning which issues to convey and what tones to use in product advertising. **Third**, a quarter of the analyzed posts explicitly sought information, and a majority of the posts engaged in an informative dialogue about oral contraceptives. The educational nature of social media is apparent for the benefit of product development. **Finally**, positive and negative sentiment about a wide range of oral contraceptive brands was varied. Increased engagement in social media listening would allow companies to learn from these praises and dismissals, associating brand names with sentiment analyses to examine best practices within the industry.

These findings match the hypotheses drawn from this study's analytical criteria. With more industry involvement in social media, the negative aspects of risk communication can be mitigated. The positive aspects of personal profiling, education, and sentiment can be strengthened. Hopefully, these findings provide a foundation for continuing the analysis of social media data in future research projects.

Section Four: Conclusion

While the 1997 regulatory shift swayed the online public sphere to the advantage of big pharma, the current lack of regulatory guidance tilts the public sphere back toward the consumer, but consumer sovereignty is not necessarily the ideal.²⁵ When consumers fail to understand the complexity of science behind the development of drugs, the industry's advertising motives, or the politics involved with industry funding, dangerous assumptions can be made. This negatively affects big pharma and poses issues for public health. Big pharma should enter into the public sphere, engaging with online health forums similar to Experience Project, Topix, and Gather for both the benefit of the industry and patient-consumers alike.

Uncertainty may still exist in employing a social media marketing strategy. Yet, this hesitation exists alongside statements like former FDA Associate Commissioner Peter Pitts' claim that "The FDA has long abandoned hopes of making platform-specific guidelines. Moving forward, pharmaceutical companies may have to settle for ambiguous rules and just decide whether the benefits of using social media outweigh its risks."²⁶ This research proves the latter. Data is readily available in the online public sphere. The pharmaceutical industry will, without a doubt, benefit from understanding the utility of social media as invaluable space for research and insight upon a currently vague regulatory backdrop. It is advisable that human-generated research continue to be conducted so big pharma may better understand today's patient-consumers.

²⁵ Sunstein, Cass. "Television and the Public Interest." *California Law Review* 88.2 (2000): 499. Print.

²⁶ Pitts, Peter in Liu, Kassity.

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