

Conference Highlight Reprint # 48-02

The Evolving Impact of Anti-Spam Legislation on Online Marketers

By John Mack

The CAN-SPAM Act of 2003 (Controlling the Assault of Non-Solicited Pornography and Marketing) became effective January 1, 2004 (see "[What You Need to Know About the New 'CAN-SPAM' Law](#)" for more information). Although the law specifically targets spam (i.e., unsolicited commercial email), it establishes requirements for those who send commercial email in general, spells out penalties for spammers and companies whose products are advertised in spam if they violate the law, and gives consumers the right to ask emailers to stop spamming them.

IBM estimates that the ratio of spam to legitimate email continuously decreased over the course of the last six months, from 83 percent in January to 67 percent in June 2005. However, many experts believe that the absolute number of spam emails being received by consumers is increasing and spam filtering vendors estimate that less than 1% of this flood of spam email complies with the national CAN-SPAM antispam law.

Many consumers view all commercial email, solicited as well as unsolicited, as spam. Or they may have forgotten that they granted the sender permission to contact them by email. In either case, your legitimate commercial email messages may be mis-interpreted as spam and intercepted by "spam filters" that have been set up to block email sent in bulk, which is often how email marketing campaigns and newsletters are sent.

Does The Law Apply to You?

You can avoid having to comply with the CAN-SPAM ACT if you have obtained adequate "affirmative consent" from the intended recipients before sending commercial emails to them. But, have you actually received the appropriate permissions from recipients for your email messages? How specific do the consent requirements and opt-out requirements have to be in order for your email not to be considered unsolicited and spam? This is especially important when a pharmaceutical company works through third parties to send commercial email on their behalf.

If you an email marketer, it is prudent for you to comply with CAN-SPAM's provisions to clearly distinguish your legitimate email advertising from spam and improve the credibility among consumers of your marketing messages. This is especially important for pharmaceutical marketers (see also "[Email Marketing Best Practices for Pharma](#)").

In the last year the FTC has issued regulations that set forth additional requirements under the federal CAN-SPAM act that you should be aware of. Hilary M. Wandall, Esq., CIPP, Director, Corporate Legal/Merck Privacy Office, Merck & Co., Inc., summarized these regulations in a recent ePharma Summit Presentation in Atlantic City, NJ.

We'll discuss these additional requirements, but first let's understand how spam and the defenses against spam, such as the CAN-SPAM Act and spam filters, can impact your online marketing campaigns.

Public Perception of Commercial Email

Spam, which is considered by most consumers as an invasion of privacy, undermines user trust and confidence in email. More importantly, spam undermines the ability of businesses to use email as a legitimate business communication tool. "Consumers often don't know if the email they are receiving is legitimate," says Wandall. "People are afraid to click on links in email because they are wary of 'phishing' and identity theft."

A recent Transatlantic Consumer Dialogue (TACD) survey of 21,000 consumers in 36 countries (including the U.S.) showed:

- 82% prefer an opt-in approach to commercial email ("governments should only allow commercial emails to be sent if the recipient has agreed in advance to receive them")
- 80% prefer that commercial email be labeled as advertising

"The European Union has adopted the opt-in approach for all commercial email precisely because of statistics like these," said Wandall.

Article 13 – AKA the “opt-in” article – of the Directive on Privacy and Electronic Communications (2002/58/EC) states that sending commercial email messages is allowed only if subscribers (i.e., recipients) have given their prior consent. “In reality,” says Mattias Durnik (MarketingProfs.com 2005), “the directive has a very soft approach to opt-in, allowing for several types of exemptions that make it possible to send marketing messages via email without having to first ask for permission.”

State Laws

Wandall pointed out that there are at least 37 state laws that regulate commercial email. “CAN-SPAM preempts certain portions of most of these laws,” said Wandall, “but does not preempt those portions prohibiting falsity or deception in commercial email or any information attached to such email.” Notwithstanding Seth Godin’s book “All Marketers are Liars” and the characterization of marketers as “BS artists” (see “[Is Pharma Marketing a Lot of BS?](#)”), it behooves email marketers to be wary of making any claims that could be interpreted as deceptive.

Wandall mentioned several specific state laws affecting general pharmaceutical marketing activities that CAN-SPAM does not preempt. These are:

- California Online Privacy Protection Act. Requires posting an online privacy policy on web sites.
- California Confidentiality of Medical Information Act. “This law,” said Wandall, “has had a great impact on the pharmaceutical industry, particularly on our ability to work with pharmacies and physicians.”
- California Consumer Privacy Protection Act. “This new law, which went into effect this year, affects call center operations.”
- Texas Medical Records Privacy Law (see “[Pharmaceutical Marketing in Texas](#)”)

FTC CAN-SPAM Proposed Rules

On May 12, 2005 the FTC published a notice of proposed rulemaking (NPRM) in which the Commission proposed the following rule provisions:

- Defining the term “person” to mean an individual, group, unincorporated association, limited or general partnership, corporation, or other business entity
- Limiting the definition of “sender” to address scenarios where a single email message contains advertisements from multiple entities.

Such a scenario might include pharmaceutical ads within an email newsletter of an independent health web site.

- Valid postal addresses include P.O. boxes and private mailboxes established pursuant to USPS regulations.
- Reducing time to honor an online opt-out request from 10 days to 3 days.
- Prohibiting senders, or anyone acting on their behalf, from charging a fee, providing information other than an email address and opt-out preferences, and taking any steps other than exercising an online opt-out, in order to opt-out and have such a request honored.

Important Definitions

“Commercial email” is any electronic mail message the primary purpose of which is the commercial advertisement or promotion of a commercial product or service (including content on an Internet website operated for a commercial purpose). Transactional or messages based on a prior business relationship are not included within this definition and are not subject to the CAN-SPAM law (see box on next page).

Criteria for determining the “primary purpose” of an email message became effective on March 28, 2005. The criteria are based on content:

CASE 1: If the content is exclusively a commercial advertisement or promotion of a commercial product or service, then the message is commercial.

CASE 2: If the message contains both a commercial advertisement and transactional or relationship content, the message is commercial IF

- the recipient reasonably concludes that the message content contains a commercial advertisement or promotion based on the subject line of the message – i.e., what you say in the subject line matters; or
- the transactional/relationship content does not appear at least in substantial part at the beginning of the message body.

CASE 3: If the message contains a commercial advertisement and other content, the message is commercial IF the recipient reasonably concludes that

- the message content contains a commercial advertisement or promotion based on the subject line of the message; or
- the primary purpose is commercial advertisement or promotion based on the

body of the message (e.g., placement of commercial content at the beginning of the message, substantial portion of message is commercial, visual prominence of commercial content within the message)

The FTC clarified that in cases where a recipient subscribes to a periodical delivered via email, transmission of that periodical to the recipient falls within the "transactional or relationship message" category of delivery of goods or services "under the terms of a transaction that the recipient has previously agreed to enter into with the sender."

Affirmative Consent

It is important to understand what affirmative consent means in the context of CAN-SPAM because this is the primary means by which commercial email is classified as spam or legitimate in the eyes of the FTC. Pay attention especially if you are using third party email lists. You essentially rely on the affirmative consent that the third party receives. People on such third party lists must have consented to receive email sent from a party other than the original party to which they gave their consent. For example, a health Web site may sign up people to receive site updates directly from them. The same sign-up form may also ask people if they consent to receive commercial email from their partners or advertisers.

Opt-Out

Opt-out means the right to request not to receive further commercial email (i.e., unsubscribe from a newsletter email list). Here are the requirements:

- Opt-out mechanism must be included in all commercial email
- Must be an internet-based mechanism (Reply email or other online mechanism (e.g., web site))
- Opt-out may permit selection of specific types of messages (e.g., different therapeutic categories) as long as right to opt-out of all commercial email messages from the sender is provided
- Must function for 30 days following transmission of the message
- Unlawful to send commercial email 10 days following opt-out request unless the recipient provides subsequent affirmative consent [May 12, 2005 FTC NPRM proposed a 3-day timeframe]

Continued on next page...

Transactional or Relationship Email Messages

A "transactional or relationship message" – email that facilitates an agreed-upon transaction or updates a customer in an existing business relationship – may not contain false or misleading routing information, but otherwise is exempt from most provisions of the CAN-SPAM Act.

Pharmaceutical companies providing safety information via unsolicited email about their product to physicians or consumers, for example, may do so without complying with CAN-SPAM as long as the product was used by the consumer or prescribed by the physician. However, it may be difficult to know if the recipient has actually used or prescribed the product.

A transactional or relationship message may also have the purpose of informing recipients of product updates or upgrades that the recipient is entitled to under the terms of a previous transaction. Providing information to physicians about a new indication for a drug, for example, may fall into this category provided that the terms of a previous transaction specified that the physician is entitled to this information. Wandall suggests that this be discussed with your legal counsel to determine if such messages would be considered spam or transactional in your particular case.

The May 12, 2005 FTC NPRM asks whether email messages whose primary purpose is to deliver newsletters or similar content (e.g., coupons) should be deemed transactional or relationship messages in situations where recipients have registered to receive such content. In comments to the FTC, the International Pharmaceutical Privacy Consortium (IPPC) – an association of pharmaceutical companies that includes AstraZeneca, Eli Lilly, Johnson & Johnson, Merck, Pfizer, and others – supports the classification of such messages as transactional or relationship messages.

- Unlawful to release email address of individual who has made an opt-out request for any purpose other than to comply with the CAN-SPAM Act of as otherwise required by law.

Many NPRM commenters, including the International Pharmaceutical Privacy Consortium (IPPC) – an association of pharmaceutical companies that includes AstraZeneca, Eli Lilly, Johnson & Johnson, Merck, Pfizer, and others – have criticized the proposed 3-day timeframe as being too short to process opt-outs.

The IPPC noted that pharmaceutical companies need time to manually review each opt-out request submitted by email to “determine whether there is other correspondence in the reply email requiring action (e.g., drug adverse event reports).”

Another problem with complying with the proposed 3-day timeframe is the necessity of manually syncing of suppression lists. In a typical marketing campaign, said IPPC, a pharmaceutical company will provide a list of email addresses to a third party vendor who initiates the transmission of the message. Opt-out requests may be received by the vendor or by the pharmaceutical company directly. If they are first received by the vendor, they must also be transmitted to the pharmaceutical company for purposes of suppressing those email addresses in the company’s database. The pharma company must also transmit the opt-outs to other vendors undertaking separate marketing campaigns. Presently, said IPPC, companies do not have in place technologies to facilitate automatic syncing of suppression lists.

ExactTarget, which provides online software for permission-based email communications to pharmaceutical and other clients, commented to the FTC that “mandating a three-day opt out processing period will unnecessarily put many well-intentioned companies out of compliance with the [CAN-SPAM] Act and impede the strategic use of email.”

Sender

Another important concept under CAN-SPAM is “sender.” A sender is a “person who initiates a commercial electronic mail message and whose, product, service, or Internet web site is advertised or promoted by the message.”

The May 12, 2005 NPRM proposed an expansion of the definition when more than one person’s products or services are advertised or promoted in a single email message. In this case, each person who is within the Act’s definition will be deemed a “sender,” except that, if only one such person is within the Act’s definition and meets one or more of

the following criteria, only that person will be deemed the “sender” of that message:

- The person controls the content of the message;
- The person determines the email addresses to which such message is sent; or
- The person is identified in the “from” line as the sender of the message.

The IPPC requested that the FTC clarify that “a company will not be deemed to control the content of one of these types of messages simply because it controls the content of the portion of the message that advertises its product, even if this content represents a substantial portion of the message.” Compliance with FDA regulations, said IPPC, requires that pharmaceutical companies have control over the content of advertising for their own products.

IPPC noted that it is not uncommon for pharmaceutical companies to co-market a product. It suggested that the FTC adopt a “safe harbor” for co-branded messages so that one company can be designated as the “sender.”

Does CAN-SPAM apply to “tell-a-friend”?

A popular method for advertisers to reach more potential customers is a form of “viral-marketing” called “forward-to-a-friend” or “tell-a-friend.” Typically this technique involves a button on a web page or in an email message that allows the reader to send the content of the web page or email message to someone’s else’s email address. Must these forward messages comply with the CAN-SPAM Act? It depends on whether or not there was an inducement for the individual to forward the email.

Here’s what the FTC has to say on the subject:

“The Commission believes that making available the means for forwarding a commercial email message, such as using a Web-based ‘click-here-to-forward’ mechanism, would not likely rise to the level of ‘inducing’ the sending of the email.

“The Commission believes that this conduct falls within the ambit of ‘routine conveyance,’ defined as ‘the transmission, routing, relaying, handling, or storing, through an automatic technical process, of an electronic mail message for which another person has identified the recipients or provided the recipient addresses.’

“The Act specifies that ‘actions that constitute routine conveyance’ do not constitute initiation of a commercial email message.

Continued on next page...

“When a company makes available the means for persons to forward a commercial email message—such as using a Web-based ‘click-here-to-forward’ mechanism—the company obviously hopes that its products or services will be advertised by interested viewers.

“Nevertheless, the Act’s legislative history regarding the definition of ‘initiate’ explains that a company is engaged in ‘routine conveyance’ rather than ‘initiating’ a commercial email message when it ‘simply plays a technical role in transmitting or routing a message and is not involved in coordinating the recipient addresses for the marketing appeal.’

“Based on this legislative history, it seems clear that a seller that simply offers a mechanism on a Web site for forwarding advertising engages in ‘routine conveyance’ when someone other than the seller identifies the recipients or provides their addresses.”

Communications Compliance Checklist

Wandall concluded her presentation with an email communications checklist that all pharmaceutical companies and their vendors may find useful:

- Designate a compliance manager in each group or division
- Determine which of your email communications are considered commercial
- Determine an appropriate scope of consent/opt-out based on:
 - Customer type
 - Physicians – Consider Company or Division as sender
 - Consumers and Patients (where permitted by law) – Consider sender as Product or Company by therapeutic category
- Range of media used for direct communications
 - Email, Fax, Telephone, Postal Mail, Internet, In Person
- Implement a comprehensive system (administrative and technical) to manage and track all applicable consents and opt-outs
- Obtain prior consent to send commercial email
- Implement a functioning online opt-out/unsubscribe mechanism
- Clearly identify the sender in all communications
- Include a valid postal address for inquiries in all communications
- Coordinate approach contractually with third party vendors

Given the amount of effort required to comply with CAN-SPAM as well as state laws governing email, some email marketers might be tempted to be less than 100% compliant with every aspect of the law.

“A prudent approach,” recommended Wandall, “is to address compliance issues by understanding and respecting the privacy expectations of your customers.”

Pharma Marketing News

Experts Consulted

The following experts were mentioned or consulted in the preparation of this article.

- **Hilary M. Wandall**, Director, Corporate Legal/Merck Privacy Office, Merck & Co., Inc., 908-423-4883, hilary_wandall@merck.com

Resource List

The following resources were consulted in the preparation of this article.

- IBM report: government, financial services and manufacturing sectors top targets of security attacks in first half of 2005; http://www.ibm.com/news/ie/en/2005/08/ie_en_news_20050804.html
- Report of TACD's online survey on spam, Oct - Dec 2003. <http://www.tacd.org/cgi-bin/db.cgi?page=view&config=admin/docs.cfg&id=225>
- 16 CFR Part 316. Definitions, Implementation, and Reporting Requirements Under the CAN-SPAM Act; Proposed Rule (May 12, 2005). <http://www.ftc.gov/os/2005/05/05canspamregformfrn.pdf>

Pharma Marketing News

Publisher & Executive Editor

John Mack
VirSci Corporation (www.virsci.com)
215-504-4164, 215-504-5739 FAX
<mailto:editor@pharmamarketingnews.com>

Pharma Marketing News (PMN) is the FREE monthly e-newsletter of the **Pharma Marketing Network**.
SUBSCRIBE TODAY

[CLICK HERE FOR ONLINE SUBSCRIPTION FORM](#)