DTC Promotion of Medical Devices
if regulated under the current DTC regulations for drugs
Federal Register Notices for Docket #2005N-0354

1. *Can the indications of a drug or device be effectively communicated to lay audience under the confines of DTC promotion and whether the limitation of benefit be properly communicated.*

   - *Presentation of information on benefits and the limitations of benefits:*

   We believe that indications for use can be effectively communicated to a lay audience, and believe that guidelines must require disclosure of limitations of benefits, if any, along with risks. Guidelines should specify that promotional materials provide a fair balance between risks and benefits, prescription products should always indicate that fact, and materials should be presented in a format and in language that is easily understood by the average lay person.

   We believe that effective guidelines can be developed by the agency, and we do not support any additional approval process for promotional material.

   If the labeling is intended for multiple user groups (health professional or consumer), the we suggest that the Health Canada guidance document for product monographs, 1989, amended May 1990 be used as a guide for developing this segmented type of DTC advertising. Using this guidance will allow the health professional to be given summary product information, indications and clinical use (including patient subsets; geriatrics and pediatrics), contraindications, warnings and precautions, adverse reactions, drug interactions, dosage and administration, over dosage, action and clinical pharmacology, storage and stability, special handling instructions, dosage forms, composition and packaging. Further, the consumer would be provided with the following types of information written in lay language summarizing the health professional information and additionally include warnings and precautions, side effects and proper use.

   - Presentation of risk information

   It is our thoughts that as indicated in the FR notice, that a fair balance of the risk information should be presented in the DTC advertisement. For devices, this fair balance should include caregiver or patient/user risk, typical electrical appliance shock risks, mechanical related risks, as well as the benefits from use of this device. We would like to propose that if these risks are listed, then a quantifiable definition of how much risk is provided for the consumer and medical professional to review. It would be helpful for the consumer to understand the extent/likelihood of the risks involved.

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As stated above, we propose that the DTC promotional material should be written to ensure the user (lay user and/or medical professional) can read and understand the ad and not be mislead by the statements made in the ad. Validation of the DTC promotional material should be performed to ensure the ad material is easily understood and not misleading.

For devices, we do not agree with the example cited, in that the "ad may continue to present positive scenes of individuals enjoying the benefits of the advertised product during the presentation of risk information"; rather, we suggest that these scenes not be shown, such that the person is not distracted from the risk information being stated.

- Use of certain standard advertising strategies:

While we agree that "coupons, free samples, …" may be good marketing strategy, this technique does not allow the target audience to focus on the ad, but rather on the "freebee" they may be getting since the ad may or may not allow them to know if the drug is right for them. Further, the use of "actor testimonials" provides a sense of realism for the drug being used and allows the viewer of the ad to better identify with the use of the drug. It is our opinion, as device manufacturers, that we would agree with this marketing strategy; however, we would want the person to understand through the DTC, to know if that device was a possible fit for them. This may be established through better education in the ad, allowing the lay person to understand if they potentially have the disease that would be treated by the device being advertised. It is our thought that by including a "layman's" definition of what disease was being treated by the device being advertised, this may result in the patient being better informed and being able to have a more knowledgeable discussion with their medical professional, and/or allow the patient to seek professional help for the "disease or condition" even if the device being advertised wasn't the right one for them.

We additionally advocate that these coupons, free samples, free trials, and money-back guarantees are acceptable practices only if they are provided along with the full DTC promotional ad (which includes information on risk and benefit) or when made along with reminder advertisements.

- *Use of comparative DTC promotion:*

As guided by the regulations for device submittals, comparative analysis is performed to demonstrate equivalence all the time. This method allows the agency to understand what are the key features of the device that would allow a substantial equivalence claim to be made. Since this is the case with the agency, it is thought that this practice may be useful for consumers to understand why one device is better than another. While it is understood that this kind of information could appear quite technical to the viewer, it can be written in such a way to state why one device has some advantage claim as compared to the competitor. Examples of an advantage claim may include: packaging details – "smaller, lighter, easier to use", or claims with regard to compliance – " patients will use this device longer per night". It is our thoughts that these soft claims may be appropriate for the DTC ads associated with devices as long as the manufacturer has the appropriate data to support the claims.

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A possible alternative, which may provide the user (lay user/medical professional) with more information, is to provide simple, easy-to-understand charts, graphs, or comparison tables to convey product comparison information to the consumer without advanced education as long as the comparison can be made accurately and completely. The ad may be misleading if all significant areas of comparison cannot be provided in simple, easy-to-understand graphics or tables. If only certain significant aspects of the comparison can be made in easily understood terms or graphics for consumers without advanced education, these tools should not be used in the advertisement (in this case a clear picture of the significant differences is not being provided since only some aspects of the comparison may be understood).

2. *Could changes in certain required prescription drug disclosures – the package insert for print "promotional" labeling and the brief summary for print advertisements – improve the usefulness of this information for consumers?*

   In addition to providing the information relative to the risks and benefits including the known or potential contraindications, some summary educational information should be provided to allow the consumer to better understand why they are taking the drug or using the device and also how the drug or device affects their medical condition.

   We suggest that package inserts and second page disclosures on prescription drugs may not be useful to the consumer population in that they are presented in print that is too small and language that is not easily understood by the general population. Inserts that are directed to the consumer in addition to information for physician use should be considered.

3. *Could changes in the requirements for disclosure of certain information in broadcast advertising improve the usefulness of this information for consumers?*

   We currently agree that the current regulations on broadcast announcements are adequate to ensure that the consumer is provided with sufficient useful information. To this information we feel the need to call attention to the viewer that this drug or device will need to be received/prescribed from a medical professional who will be able to explain the risks and benefits of the drug or device being provided.

   Information required to be disclosed related to risks and contraindications should be provided in a manner that is not distracting; that is, so that the viewer can focus on the information rather than visual distractions.

4. *Is there a way to make information in DTC promotion of medical devices more useful to consumers?*

   As is the case with the regulations for DTC promotion for drugs, risk and benefit information, as well as intended use, indications for use, use population, contraindications and a description of the disease state/condition being treated would be necessary for devices.

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5. *As new communication technologies emerge, they create opportunities for novel approaches to DTC promotion. What issues should the agency consider with regard to the effect of these technologies on DTC promotion.*

   It is our collective opinion that any DTC promotional material be delivered to the consumer commensurate with the agency regulations. This would require at a minimum the requirements for the "brief ads" as well as providing a "fair balance" of risk and benefit information to the end viewer. Respironics recommends that Agency guidelines for DTC promotional material should be clear. Respironics does not advocate review and approval of DTC promotional material by the Agency.

   With new communication technologies, such as text messaging and email spamming advertisements, the agency should be concerned with consumer privacy and their right to request to not be solicited. Much like a "Do not call list" has been established for phone telemarketers, other protections or such lists may be needed for consumers to protect them from new approaches to DTC promotion.

   Also, with children increasingly using email and owning cell phones this population needs to be carefully considered when evaluating the issues of novel approaches of DTC advertising.

6. *What action should FDA take when companies disseminate violative promotional material to consumers?*

   Similar to what is current practice by the agency, we are favoring this practice, in that the agency should issue a warning letter to the company disseminating violative promotional materials. If distribution of the violative materials does not cease within a reasonable period upon receipt of the warning letter, the company should be required to make a corrective statement to the public (via an advertisement in print or broadcast – depending on the form in which the violative material was disseminated) and/or invoke monetary penalties.

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