

**Centers for Disease Control and Preventions Comments on the
FDA Guidance Document on Condom Labeling
[Docket No. 2004D-0555]**

P4. Second bullet from the bottom of the page: delete “pull it” – may lead to breakage. Suggest: **“Place the condom on the head of the penis and unroll ~~or pull~~ it all the way to the base.”**

This change is also appropriate for page 22, under “Package Insert”, 2nd bullet.

P7, Table 1:

Identified Issues	Recommended mitigation measures
<p>2a. Delete “(HIV/AIDS).” Suggest: “(HIV, the virus that causes AIDS)”</p>	<p>2a. Delete “can greatly reduce, but do not eliminate, the risk of HIV transmission.” Suggest: “Labeling should indicate that latex condoms, can greatly reduce, but do not eliminate, the risk of HIV transmission. when used consistently and correctly, are highly effective in preventing the sexual transmission of HIV, the virus that causes AIDS.”</p>
	<p>2b. Suggest: “Labeling should indicate that latex condoms, when used consistently and correctly, can reduce the risk of STD transmission . . . “</p>
<p>2c. Delete “the vagina and”. The existing language is awkward and not accurate. Suggest: “STDs, such as chlamydia and gonorrhea, that are transmitted to or from the penis by contact with the vagina and through infected vaginal and genital fluids.”</p>	<p>2c. Delete “the vagina or” and move the phrase “such as chlamydia or gonorrhea.” Suggest: “Labeling should indicate that latex condoms, when used consistently and correctly, can reduce the risk of STDs such as chlamydia or gonorrhea that are transmitted to or from the penis by contact with the vagina or through vaginal and genital fluids.” such as chlamydia and gonorrhea.</p>
<p>2d. Delete “as well as by contact with the penis.” Suggest: “STDs, such as genital herpes and human papillomavirus (HPV) infection, that can be transmitted by contact with skin outside the area covered by a condom.” , as well as by contact with the penis.”</p>	<p>2d. Suggest indicating that condoms don’t prevent transmission that results from contact outside the area covered by a condom, and indicate that, based on recent research results, condoms may provide some reduced risk of acquiring HPV infection.</p> <p>Suggest: “Labeling should indicate that latex condoms do not offer protection for infections that are acquired or spread by contact with skin outside the area covered</p>

	<p><u>by a condom; therefore, latex condoms may provide less protection for those STDs, such as genital herpes and HPV, that may be transmitted by such contact. Labeling should clarify that correct and consistent use of condoms may provide some benefit for these STDs, such as reduced risk of herpes infection or reduced risk of acquiring HPV infection or developing HPV-related diseases.</u></p>
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Note: These language suggestions are relevant in several other locations in the document; suggest changes consistent with above recommendations in the following places:

P 12:

-Paragraph (under 2b): “The retail package of condoms should indicate that there are many types of STDs and that latex condoms, **when used consistently and correctly**, can help to prevent the transmission of STDs that are spread to and from the penis.

- Indented paragraph (under 2b): “*Important information: There are many types of sexually transmitted diseases (STDs). . . A latex condom, **when used consistently and correctly**, can reduce the risk of STD transmission to or from the penis.*

2c. “STDs transmitted ~~to or from the penis by contact with the vagina and~~ **through infected vaginal and genital fluids**”

-Paragraph (under 2c): “The package insert should include a statement explaining that latex condoms, **when used consistently and correctly**, can help prevent the transmission of STDs that are spread ~~to or from the penis by contact with the vagina and~~ **through infected vaginal and genital fluids.**”

- Indented paragraph under 2c: “*Important information: Latex condoms, **when used consistently and correctly**, can reduce the risk of sexually transmitted diseases (STDs), such as chlamydia and gonorrhea, that are spread ~~to or from the penis by direct contact with the vagina and~~ **through infected vaginal or genital fluids.***”

P 13. 2d. Paragraph (1st, 4th-5th sentences)

Suggest:

“The package insert should indicate that condoms may provide less protection for certain STDs”

“For example, **correct and consistent use of a latex condom, may lower the risk of catching or spreading genital herpes. ~~Using a~~ **Correct and consistent use of a latex condom** also may lower the risk of acquiring HPV infection or developing HPV-related diseases, such as genital warts and cervical cancer.**

Indented, italicized paragraph:

Suggest: *“Important information: Condoms may provide less protection for certain STDs, including genital herpes and human papillomavirus (HPV) infection, that can also be spread by contact with infected skin outside the area covered by the condom. Condoms cannot protect against these STDs when they are spread in this way. Using latex condoms every time you have sex may still give you some benefits against these STDs. For example, using a correct and consistent use of a latex condom may lower your risk of catching or spreading genital herpes. Using a Correct and consistent use of a latex condom also may lower your risk of acquiring HPV infection or developing HPV-related diseases, such as genital warts and cervical cancer.”*

P. 14 – 2nd sentence (top of page):

Suggest: *“Latex condoms, when used consistently and correctly, can also reduce the risk of other sexually transmitted diseases (STDs), such as chlamydia and gonorrhea that are spread to or from the penis by direct contact with the vagina and through infected vaginal and genital fluids.”*

P14. 2nd para/last sentence:

Suggest: *“Using a Correct and consistent use of a latex condom also may lower your risk of acquiring HPV infection or developing HPV-related diseases, such as genital warts and cervical cancer.”*

P. 23, Under “important information” in “Package Insert”:

1st para/last sentence: Suggest: *“Latex condoms can also reduce the risk of other sexually transmitted diseases (STDs), such as chlamydia and gonorrhea, that are spread to or from the penis by direct contact with the vagina and through infected vaginal and genital fluids.”*

2nd para/last sentence: Suggest: *“Using a condom also may lower your risk of acquiring HPV infection or developing HPV-related diseases, such as genital warts and cervical cancer.”*

Table 2:

Identified Issues	Recommended Mitigation Measures
2c. Existing language suggests that condoms with N-9 should not be used for anal sex, period. This suggests that it is better not to use a condom for anal sex than use a condom with N-9.	2.c Suggest: <u>“Labeling should inform users that N-9 can irritate the rectum and therefore latex condoms without N-9 should be used for anal sex. However, labeling should indicate that although condoms with N-9 may be associated with greater risk of getting HIV/AIDS from an infected partner when compared with condoms without N-9, it is safer to use a condom with N-9 than no condom at all.”</u> “Labeling should inform users that condoms with N-9 should not be used for anal sex because N-9 can irritate the rectum and may increase the risk of getting HIV/AIDS from an infected partner.”

	<p>Note: This approach is consistent with language used by CDC before, regarding N-9, although it was not specific to anal sex.</p> <p>http://www.cdc.gov/hiv/pubs/mmwr/mmwr11aug00.htm</p> <p>“.....a condom lubricated with N-9 is clearly better than using no condom at all. The protection provided by the condom against HIV far outweighs the potential risk of N-9....”</p>
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This change is applicable elsewhere in the document, as follows:

P. 17

2c: Indented paragraph

Suggest: **“Nonoxynol-9 Warning: *N-9 can irritate the rectum and therefore latex condoms without N-9 should be used for anal sex. However it is safer to use a condom with N-9 than no condom at all.*”**

You should not use condoms with nonoxynol-9 (N-9) for anal sex. N-9 can irritate the rectum and may increase the risk of getting HIV/AIDS from an infected partner.”

P 18: Under “N-9 warning”: 3rd bullet:

Suggest: ***N-9 can irritate the rectum and therefore latex condoms without N-9 should be used for anal sex. However it is safer to use a condom with N-9 than no condom at all.*** *You should not use condoms with N-9 for anal sex. N-9 can irritate the rectum and may increase the risk of getting HIV/AIDS from an infected partner.*

P. 21 “Nonoxynol-9 Warnings”: 3rd bullet:

Suggest: ***N-9 can irritate the rectum and therefore latex condoms without N-9 should be used for anal sex. However it is safer to use a condom with N-9 than no condom at all.*** *You should not use condoms with N-9 for anal sex. N-9 can irritate the rectum and may increase the risk of getting HIV/AIDS from an infected partner.*

P. 23 Last sentence: Suggest: ***N-9 can irritate the rectum and therefore latex condoms without N-9 should be used for anal sex. However it is safer to use a condom with N-9 than no condom at all.*** *You should not use condoms with N-9 for anal sex. N-9 can irritate the rectum and may increase the risk of getting HIV/AIDS from an infected partner.*

Other Comments:

p. 11 The table entitled, “Pregnancy rates for barrier birth control methods” currently includes data on typical use pregnancy rates only. Given that the labeling document discusses the importance of consistent and correct use (see pp. 4, 10, and 11), perfect use rates of pregnancy also should be included.

p. 13 Under 2d, the italicized language, 3rd sentence currently reads, “Using latex condoms every time you have sex may still give you some benefits against these STDs.”

Suggest: **“Using latex condoms every time you have sex may still give you some benefits against these STDs when transmission would involve areas that are covered by the condom.”**

p. 14 Under “3. Incorrect or Inconsistent Use,” The current bullet “Use a new condom every time you have sexual intercourse *or other acts between partners that involve contact with the penis,*” is both vague and unclear.

Recommend shortening first bullet to: **“Use a new condom every time you have sexual intercourse”** or clearly specify different types of intercourse (i.e., oral, vaginal, and anal).

p. 14. The reference for the workshop on condom effectiveness, led by NIH with CDC and FDA involvement, should be cited as:

National Institute of Allergy and Infectious Diseases. Workshop Summary: Scientific Evidence on Condom Effectiveness for Sexually Transmitted Diseases (STD) Prevention. National Institute of Allergy and Infectious Diseases. Workshop Summary: Scientific Evidence on Condom Effectiveness for Sexually Transmitted Diseases (STD) Prevention. July 20, 2001. <http://www.niaid.nih.gov/dmid/stds/condomreport.pdf>.