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Policy Statement on Unapproved Drugs

Men's Health Network is aware that unapproved drugs that have never been evaluated by the U.S. Food and Drug Administration (FDA) are commercially available, and in some cases, proactively marketed to both consumers and physicians, even when an FDA-approved alternative is currently available. Because unapproved drugs are not regulated or monitored the way modern pharmaceutical products are today, it is the position of Men's Health Network that they may pose a serious threat to the public health.

Unapproved drugs are not required to meet the same manufacturing standards as approved drugs. In addition, certain unapproved drugs have been associated with the death of patients who took them. In one example involving the use of unapproved colchicine, an unapproved drug used for centuries to treat gout and Familial Mediterranean Fever (FMF), the FDA reported 169 deaths[i] associated with its use. Another unapproved drug, carbinoxamine, a sedating antihistamine, was associated with 21 reports of death in children under two years of age[ii]. Levothyroxine sodium, used to treat hyperthyroidism, was recognized by FDA as having issues with formulation and stability that were only uncovered when the drug was evaluated through FDA-sanctioned clinical trials[iii].

As part of its ongoing safety initiative, FDA issued a final guidance document (Compliance Policy Guide, or CPG) in June, 2006[iv], outlining its approach to addressing medicines that are marketed without required FDA approval. The FDA's right to enforcement action to stop the manufacture of unapproved drugs due to safety concerns was detailed in this CPG. According to the CPG, "FDA intends to evaluate on a case-by-case basis whether justification exists to exercise enforcement discretion to allow continued marketing for some period of time after FDA determines that a product is being marketed illegally." [v]

In the interest of protecting the health of all Americans, we strongly urge FDA to take urgent action against the manufacturers of unapproved drugs as soon as FDA-approved alternatives become available.

Aside from the lack of clinical efficacy and safety data to support their use, in our view, the continued manufacture and marketing of unapproved drugs following the approval of an FDA-approved alternative puts the public at risk for several reasons. By skirting the FDA approval process, unapproved drugs lack the specific quality controls of an FDA-approved drug, including purity and consistency, as well as important manufacturing oversight that ensures the appropriate amount of active drug in each tablet. In addition, unapproved drugs are not required to have dosing information that aligns with current medical practice. In the case of unapproved colchicine, medically unnecessary and toxic doses are recommended in the prescribing information supplied by their manufacturers.[vi] Unapproved drugs are also not subject to FDA's post-market surveillance process, which "seeks to identify problems that were not observed or recognized before approval and any problems that may arise because a drug may not be used as described in the drug labeling, or because a drug is being manufactured incorrectly." [vii] Finally, drug-drug interactions have not been evaluated for many unapproved drugs. As a result, unapproved drugs may represent a real risk to patients.

In conclusion, Men's Health Network believes that unapproved drugs that remain on the market with known hazards represent a serious danger to the health of the American public. We urge FDA to exercise its enforcement authority toward the manufacturers of unapproved drugs, swiftly and consistently, when an FDA-approved alternative is made available, in the interest of public safety.

<u>About Men's Health Network</u>

Men's Health Network (www.menshealthnetwork.org) is a national non-profit organization whose mission is to reach men and their families where they live, work, play, and pray with health

prevention messages and tools, screening programs, educational materials, advocacy opportunities, and patient navigation.

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[i] "Information for Healthcare Professionals: New Safety Information for Colchicine," U.S. Food and Drug Administration Alert, July 30, 2009 http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/DrugSafetyInformationforHeathcareProfessionals/ucm174315.htm (accessed March 5, 2010)

[ii] "Questions and Answers about Unapproved Drugs and FDA's Enforcement Action Against Carbinoxamine Products," U.S. Food and Drug Administration document, June 8, 2006 http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/SelectedEnforcementActionsonUnapprovedDrugs/ucm119635.pdf (accessed March 5, 2010)

[iii] "Questions and Answers on Levothyroxine Sodium Products," U.S. Food and Drug Administration document, October 3, 2007 http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm161266.htm (accessed March 5, 2010)

[iv] "Marketed Unapproved Drugs – Compliance Policy Guide," Sec.440.100, U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM070290.pdf (accessed March 9, 2010)

[v] Ibid, Sec. B. (p.4) "Notice of Enforcement Action and Continued Marketing of Unapproved Drugs" (accessed March 9, 2010)

[vi] "FDA Alert: Information for Healthcare Professionals. New Safety Information for Colchicine." U.S. Department of Health and Human Services, Food and Drug Administration, July 30, 2009 http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/DrugSafetyInformationforHeathcareProfessionals/ucm174315.htm (Accessed March 9, 2010)

[vii] "An FDA Guide to Drug Safety Terms," U.S. Department of Health and Human Services, Food and Drug Administration, Consumer Updates page http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm107970.htm (updated June 18, 2009; accessed March 9, 2010)