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FDA Issues Warning About an Ingredient in Cold Remedies and Diet Drugs

The Dangers of PPA:

Phenylpropanolamine ("PPA") is a drug that has been used widely for years in non-prescription diet pills and cold remedies.¹ The drug is a central nervous system stimulant that can increase the heart rate and blood pressure.² PPA works as a decongestant because it shrinks a swollen congested nose by narrowing the blood vessels.³ The effectiveness of PPA as a diet drug has been questioned for years.⁴ A survey of the readers of *Consumer Reports* in the mid-1990s revealed that of those who had tried PPA-based diet pills like Acutrim and Dexatrim, fewer than five percent were satisfied.⁵ Evidence shows that these drugs typically result in trivial weight loss, if any.⁶

On November 7, 2000, the Food and Drug Administration ("FDA") publicly warned American consumers to stop using the many medications containing this ingredient.⁷ The reason for the ban: PPA, according to a recent study, increases the risk of stroke. In extreme cases, a spike in a person's blood pressure, caused by taking medication containing PPA, ruptures an artery in the brain, causing a hemorrhagic stroke.⁸

The FDA and the Consumer Healthcare Products Association ("CHPA"), a group which represents drug manufacturers, agreed five years ago to this study of PPA's link to strokes by researchers at Yale University.⁹ The study was to be published in the December 21, 2000, edition of the *New England Journal of Medicine*, but the findings were so compelling they were released seven weeks early: 18- to 49-year-old victims of hemorrhagic strokes were two to fifteen times more likely to have taken PPA within three days of the stroke.¹⁰ In addition,

researchers estimate that the link between PPA and strokes is even stronger because the study excluded stroke victims who had died or lost their ability to communicate.¹¹ According to the study, between 200 and 500 strokes a year were linked to the ingredient and the risk of stroke grows when the dosage exceeds 75 milligrams a day.¹²

In addition to the risk of PPA alone, medical studies done even before 1995 have shown that combining caffeine and PPA can be dangerous.¹³ Both PPA and caffeine, as stimulants, cause blood pressure to rise.¹⁴ Those who combined the equivalent of a PPA diet pill and three cups of coffee show blood-pressure increases into the hypertension range.¹⁵ As a result of this discovery, ten years ago the FDA banned caffeine from PPA diet pills.¹⁶ But, diet pills never carried a warning to alert consumers that the combination of caffeine and diet pills — a veritable norm for dieters — could be dangerous.¹⁷

FDA Action Based on the Study:

Based on the FDA advisors decision to classify PPA as unsafe, the FDA will likely ban nonprescription PPA.¹⁸ The FDA is not bound by the decisions of its advisors, but does usually follow them.¹⁹ The process is not so speedy, however. In order to permanently ban the drug, the FDA must first issue a new regulation governing over-the-counter products and seek public comment.²⁰ Then, the FDA must initiate separate proceedings to remove the ingredient from prescription drugs.²¹ The process could take months and the FDA issued the recent warning to give consumers immediate notice of the risks of PPA.²²

For now, the FDA has asked drug companies to remove PPA from the market.²³ The CHPA has continued to defend the safety of PPA when used properly, but its member drug companies *are* acknowledging and acting on the warning issued by the FDA.²⁴ Manufacturers knew

three weeks before the warning was given, when the FDA's advisors voted PPA unsafe, that this FDA move was coming.²⁵ Bayer has already agreed to reformulate its Alka-Seltzer Plus products to exclude PPA, and Bristol-Myers Squibb and SmithKline Beecham have both stated that they would stop marketing PPA-containing medications.²⁶ The makers of Dimetapp, Whitehall-Robinson Healthcare, quit shipping Dimetapp containing PPA.²⁷ Other manufacturers of PPA-containing medications have not yet made public their plans to deal with the warning.²⁸ All of them are bracing for possible lawsuits alleging they marketed a product they knew to be unsafe.²⁹ Walgreen Co. and CVS Pharmacy began pulling all PPA-containing medications from their shelves in response to the FDA's warning.³⁰ Makers of prescription drugs containing PPA have also been asked by the FDA to stop selling the drugs.³¹

What Consumers Should Know:

PPA is found in cold medications and diet drugs. Some of the most common medications containing PPA (in at least one form of the medication) include Acutrim, Dexatrim, Triaminic, Contac, Tavist-D, Propagest, Alka-Seltzer Plus, and Robitussin.³²

According to the Yale University study, the risk for the average dieter or cold sufferer when using PPA is very small.³³ Approximately 6 billion doses of PPA are sold each year in the U.S., while the study estimates between 200 and 500 young lives will be saved by the recall.³⁴

However, the risk is greater than any benefit gained from the use of the drug.³⁵ While hemorrhagic strokes are the least common type, they are most devastating.³⁶ They are often fatal and can leave victims severely disabled.³⁷ Hemorrhagic strokes are very rare in young people.³⁸ According to FDA estimates, of the 130 million Americans ages 18-49, 10,400 suffer a hemorrhagic stroke

each year.³⁹ The risk of such a stroke increases with age especially when combined with high blood pressure, smoking, alcohol, and use of blood thinning medicines.⁴⁰

Why the FDA Approved PPA in the First Place:

Prior to this most recent controversy over the risks of the drug, PPA was permitted to be marketed as a safe and effective over-the-counter (“OTC”) appetite suppressant by the FDA.⁴¹ The FDA permitted daily dosages up to seventy-five mg. per day in any variety of dosing regimens.⁴² Because of this FDA approval, one would assume that there had been extensive well-controlled testing of the safety and effectiveness of PPA and its dosages.⁴³ But, this is not the case.⁴⁴ PPA became an approved drug because, when the FDA was given control over OTC drugs, PPA was marketed in 75 milligrams per day dosages, and the FDA chose to freeze the marketplace at the dosage limits that were available at that time.⁴⁵ There was no extensive testing.⁴⁶

What the Public *Could Have Known*:

The first indications of problems with use of PPA came in the early 1980's.⁴⁷ Medical journals began citing puzzling cases of young women, with no previous health problems, who were having strokes within a few days of ingesting diet drugs.⁴⁸ The FDA, itself, has record of forty-four cases of hemorrhagic stroke among PPA users in the past thirty years.⁴⁹ And, because the FDA learns of fewer than ten percent of the serious side effects drugs cause each year, those numbers are only the beginning.⁵⁰ According to some attorneys representing plaintiffs in suits relating to PPA and strokes, drug makers have kept the public unaware of the danger by insisting on confidentiality as a condition of settling lawsuits.⁵¹ These agreements have been described as agreements which obstruct the free flow of information about the

dangers of diet pills.⁵² Because of the number of cases and the history of litigation over the chemical, critics of PPA have argued for years that the FDA should have acted long ago not just to restrict but to stop sales of diet pills containing PPA.⁵³ But, the FDA was more cautious and insisted that there was not conclusive evidence.⁵⁴ U.S. Representative Ron Wyden from Oregon, who had been trying to restrict the sale of PPA diet pills for years, said in a 1994 article that the FDA was sidestepping a decision on whether such drugs should be readily available.⁵⁵

Consumers or Guinea Pigs?:

According to experts, the recent FDA warning underscores an aspect of drug testing many do not understand: The American people serve as one huge clinical trial.⁵⁶ Even when a drug has been tested by the FDA, side effects often do not surface until thousands have taken it for a considerable length of time.⁵⁷ During the past three years, the FDA has banned or all-but-banned common drugs after life-threatening side effects were reported years after the drugs hit the market.⁵⁸ An example is fen-phen. Fen-phen is a combination of two prescription weight-loss pills, fenfluramine and phentermine, that had been taken separately since the 1960's.⁵⁹ After 1992, dieters began taking the two together.⁶⁰ In 1997, the FDA pulled fenfluramine from the market after the combination was linked to leaky heart valves and an often fatal lung disease, pulmonary hypertension.⁶¹ By the time the drug was banned, however, approximately 6 million Americans were taking the drug.⁶²

Keeping track of side effects is something the FDA is trying to improve.⁶³ Many researchers claim that the delay in banning PPA shows the system is too weak and takes too long.⁶⁴ The program that the FDA uses to keep track of side effects, MedWatch, relies on doctors, pharmacists and patients to report so-called adverse incidents

from prescription and non-prescription drugs, and even the FDA acknowledges that unpredicted side effects remain under-reported for years.⁶⁵

In order to improve the system, the FDA has added money and staff to its reporting system and has asked for more resources, but Congress has been reluctant to provide them.⁶⁶ According to experts, the FDA needs epidemiologists and statisticians and doctors interested in developing a system that reports these things in a sensible, scientific way earlier.⁶⁷ In addition, it is possible that the FDA had trouble getting research about PPA from the drug industry, which maintains it is safe if used properly.⁶⁸ While the FDA today has record of only forty-four cases of PPA-related strokes a in the past thirty years, the fact that physicians, 15-year-old medical reports and the recent study by Yale University have chronicled dozens more makes the agency seem more like the last to know than a protective watchdog.⁶⁹

Message to Consumers:

For now, consumers should check their medicine cabinets and the shelves of drug stores to make certain that they are not purchasing medication containing PPA. Though the risk of stroke is a statistically small one, it is not one worth taking according to the most recent studies and the judgment of the FDA. In addition, consumers should always beware. Dr. Gary Zaloga has even gone so far as to say that there's no such thing as a really safe medicine.⁷⁰ His advice: If you're clearly taking medicine chronically, you probably ought to find out more about it.⁷¹

If faced with the sniffles, one can, according to experts, safely take medications with the ingredient pseudoephedrine.⁷² Studies have also indicated that zinc can help a person beat a cold.⁷³ Unfortunately, there are no over-the-counter alternatives for diet pills, so dieters

will have to consult a doctor about prescription-only alternatives.⁷⁴

Endnotes

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2. Wes Allison, *Drugs= Ill Effects Often Discovered Years Later*, ST. PETERSBURG TIMES, Nov. 11, 2000, at 1A.

3. Michael Breen, *Cold Medications Can Be Dangerous*, CHI SUNTIMES, Nov. 5, 2000, at 42.

4. *Drugstore Deceptions: Separating Hype From Hope*, CONSUMER REP. ON HEALTH, March, 1995, Vol. 7, No. 3, p. 32 - 34.

5. *Id.*

6. *Id.*

7. Neergaard, *supra* note 1.

8. Allison, *supra* note 2.

9. *Id.*

10. *Id.*

11. *Id.*

12. Interview by Andria Hall on CNN Worldview of Dr. Edward Kernan, associate professor of medicine at Yale University, Oct. 21, 2000 (quote of Andria Hall).

13. Diane Hembree, *Dying to Lose Weight—Popular, Over-the-Counter Weight-Loss Pills Have Been Linked to Crippling*, SAN. FRANCISCO CHRON., Dec. 4, 1994, at S1/Z1.

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17. *Id.*
18. Medical Letter on the CDC & FDA, Nov. 12, 2000.
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22. *Id.*
23. FDA: *Issues Consumer Warning on Products Containing PPA*, AM. HEALTH LINE, Nov. 7, 2000.
24. *Id.*
25. Neergaard, *supra* note 1.
26. FDA: *Issues Consumer Warning on Products Containing PPA*, *supra* note 23.
27. Neergaard, *supra* note 1.
28. *Id.*
29. Breen, *supra* note 3.
30. Neergaard, *supra* note 1.
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32. *Id.*
33. Medical Letter on the CDC & FDA, *supra* note 18.
34. Neergaard, *supra* note 1.
35. Jeremy Olson, *Diet, Cold Pills Pulled After Warning — What to Look For*, OMAHA WORLD-HERALD, at 1.
36. Medical Letter on the CDC & FDA, *supra* note 18.
37. *See id.*
38. *Id.*

39. *Id.*
40. *Id.*
41. Thompson Medical Co., Inc. v. CIBA-GEIGY Corp., 643 F.Supp. 1190, 1192. (S.D.N.Y. 1986).
42. *Id.*
43. *Id.*
44. *Id.*
45. *Id.*
46. *Id.*
47. Medical Letter on the CDC & FDA, *supra* note 18.
48. *See id.*
49. *Id.*
50. *Id.* (comment by the FDA's Dr. Lois La Grenade).
51. Hembree, *supra* note 13.
52. *See id.* (quoting Donald Shapiro, attorney who represented one plaintiff, Michael Cannata, in a suit against Thompson Medical Co. after Mr. Cannata's wife died of a hemorrhagic stroke after taking PPA).
53. *Id.*
54. *Id.*
55. *Id.* (quoting U.S. Representative John Wydon).
56. Allison, *supra* note 2.
57. *See id.*
58. *Id.*
59. *Id.*

60. *Id.*

61. *Id.*

62. *Id.*

63. *Id.*

64. *Id.*

65. *Id.*

66. *Id.*

67. *Id.* (quoting Dr. Paul E. Leaverton, professor of epidemiology at the University of South Florida in Tampa, who studies clinical trials).

68. *Id.* (comment by Laura Bradbard, FDA spokesperson).

69. *Id.*

70. *Id.* (quoting Dr. Gary Zaloga, a critical care doctor in Maryland who has treated patients with PPA-related strokes).

71. *Id.*

72. Breen, *supra* note 3.

73. *See id.*

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