



STATE OF NEW YORK DEPARTMENT OF HEALTH

Corning Tower

The Governor Nelson A. Rockefeller Empire State Plaza

Albany, New York 12237

Antonia C. Novello, M.D., M.P.H., Dr.P.H.
Commissioner

Dennis P. Whalen
Executive Deputy Commissioner

July 23, 2003

Craig M. Burrridge, M.S., CAE
Executive Director
Pharmacists Society of the State of New York
210 Washington Avenue Extension, Suite 101
Albany, New York 12203

DOH GC Opinion No. 03-03
Classification of Human Chorionic Gonadotrophin

Dear Mr. Burrridge:

This responds to your letter of April 14, 2003 which requested on behalf of the Pharmacists Society of the State of New York ("PSSNY") a legal opinion whether the Commissioner of Health may, by regulation, reclassify the drug HCG from Schedule II to Schedule III of Public Health Law ("PHL") Article 33. I assume that by "HCG" you mean human chorionic gonadotrophin, also known as chorionic gonadotrophin. HCG is currently classified as a Schedule II substance by subdivision (j) of Schedule II of PHL § 3306. Pursuant to various provisions in Article 33, Schedule II substances are subject to more stringent conditions for their prescription than are Schedule III substances.

You state that PSSNY believes that the Commissioner has the rulemaking authority to reclassify HCG from Schedule II to Schedule III based on PHL § 3307, which you quoted in full. You did not specify which of its four subsections you believe applies to HCG. Clearly, subsection (1), which applies to certain substances listed on Schedules III or IV, does not apply to HCG which is listed on Schedule II. Subsections (2) and (3) apply to certain compounds, mixtures or preparations containing a stimulant substance listed in paragraph (c) of Schedule II or a narcotic antagonist substance, respectively. HCG, is not itself either such a stimulant substance or a narcotic antagonist substance and is not a component of any actual compound, mixture or preparation known to this Department's Bureau of Controlled Substances to contain either such a stimulant substance or a narcotic antagonist substance. Accordingly, subsections (2) and (3) do not apply to HCG.

The only remaining provision of § 3307 is subsection (4) which provides:

"(4) The commissioner may by regulation exempt or reclassify any compound, mixture or preparation containing any substance listed in

subdivision (h) or (j) of Schedule II of [PHL § 3306] as a Schedule III, IV or V substance if (a) the compound, mixture or preparation contains one or more active medicinal ingredients not found in subdivision (h) or (j) of Schedule II of [PHL § 3306]; and (b) such ingredients are included therein in such combinations, quantity, proportion or concentration as to substantially reduce the potential for abuse.”

Subsection (4) might apply to any compound, mixture or preparation containing HCG, a substance listed in subdivision (j) of Schedule II, but only if it meets the two conditions set forth above. HCG does not exist in any compound, mixture or preparation known to this Department’s Bureau of Controlled Substances to contain active medicinal ingredients not found in subdivision (h) or (j) of Schedule II and included in a manner to reduce substantially the potential for abuse. Accordingly, subsection (4) does not permit the Commissioner to reclassify HCG from Schedule II to Schedule III.

Based on the foregoing, and the facts as reported to me, it is my opinion that the Commissioner of Health does not have the power under PHL § 3307 to reclassify HCG from Schedule II to Schedule III. No other provision of law permits the Commissioner so to reclassify HCG. Accordingly, unless it can be shown to this Department that HCG can be combined with other substances in a way which might make the resulting compound, mixture or preparation subject to PHL § 3307(2), (3) or (4), the only way that HCG could be reclassified from Schedule II to Schedule III would be pursuant to a change in the statute.

I note that legislation (Senate 4159a - Assembly 8146a) reclassifying HCG has been approved by each house of the New York State Legislature, but the Governor has not yet acted to approve or veto that legislation.

This conclusion is based on the facts set forth herein and any change in those facts might result in a change of the conclusion.

Very truly yours,

Donald P. Berens, Jr.
General Counsel

Mr. Burrige

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