February 7, 1967

TO: RICHARD J. BARTLETT

FROM: Peter J. McQuillan

I have read the attached letter of Joseph F. Carlino and his accompanying memorandum. Former Penal Law §1747-a was placed in the Education Law (as §6804-a) by our 1965 Transfer Bill. If this section had merely proscribed the sale of "appliances, drugs or medicinal preparations intended or having special utility for the prevention of venereal diseases," we would have recommended repeal, rather than transfer, because such conduct is adequately regulated in Article 137 of the Education Law. However, because of the words "and/or" in this section, it would appear that this section also proscribes the sale of "appliances, drugs or medicinal preparations...used in gynecological hygiene or treatments." It is less than clear whether Article 137 is applicable to such a sale.

When preparing the Transfer Bill in 1962, I did not explore this lack of clarity nor did I specifically raise the question with the Education Department. Instead, I merely informed them that we planned to transfer this provision without substantive change to the Education Law. The Department had no objection to this recommendation (Correspondence attached).

The memorandum accompanying Mr. Carlino's letter correctly points out that there is no need for a special provision dealing with the sale of preparations designed for the treatment of venereal disease. The apparent reason for this conclusion is that Education Law §6804(3)(c), §6805 and §6821(4) proscribe the sale of "drugs" and "devices" by other than registered pharmacists. "Drugs" is defined in Education Law §6801, subdivision 14, as follows:

> 14. "Drugs" means:
>
> a. Articles recognized in the official United States pharmacopoeia, official homeopathic pharmacopoeia of the United States, or official national formulary, or any supplement to any of them.
>
> b. Articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals.
>
> c. Articles (other than food) intended to affect the structure or any function of the body of man or other animals.

> d. Articles intended for use as a component of any article specified in paragraphs a, b, or c; but does not include devices or their components, parts or accessories.

Subdivision 26 of this section defines "device" as follows:

> 26. "Device" except when used in subdivision eight of section sixty-eight hundred twenty-one, means instruments, apparatus, and contrivances, including their components, parts and accessories, intended:
>
> a. For use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; or
>
> b. To affect the structure or any function of the body of man or other animals.

If (to use the language of new Education Law §6804-b) "appliances, drugs or medicinal preparations...used in gynecological hygiene or treatments" are within the meaning of the defined terms "drugs" and "device," supra, then the repeal of §6804-b would be meaningless, i.e., repeal would effectuate no change in the law whatsoever. (Indeed, if such be the case, §6804-b should be repealed on grounds of redundancy.) An explicit amendment to the Education Law would be required to authorize the sale of such appliances, drugs or preparations in places other than those registered by the state board of pharmacy.

If, on the other hand, such appliances, drugs or preparations are not "drugs" or "devices," then only §6804-b proscribes their sale.

It seems to me that Mr. Carlino might initially seek an interpretation or ruling from the Education Department as to whether these articles are "drugs" or "devices," within the meaning of §6801(14)(26). In his memorandum he points out that there are "a number of douche and other feminine hygiene preparations available that are perfectly safe under both the Federal and State Food and Drug Acts being sold in non-drug outlets throughout the country." Do these states have statutes similar to §6801(14)(26)? If so, then feminine hygiene preparations have been found in these states not to be "drugs" or "devices," or legislation in these jurisdictions has expressly authorized non-drug outlet sales. Such data would be useful in seeking an opinion from the Education Department.

I would suppose that Mr. Carlino could urge the Education Department that feminine hygiene preparations are solely "cosmetics" within the meaning of §6801(15); or, perhaps, that if they are "drugs" within the meaning of §6801(14), that they are "proprietary medicines" and are,

accordingly, exempt from regulation under Article 137 [See §6816(2)(c)].

If the Education Department rules that such preparations are within the meaning of §6801(14)(26), and are not "proprietary medicines," then two amendments to the Education Law are necessary to effectuate Mr. Carlino's purpose: (1) a repeal of §6804-b, and (2) an amendment to §6801(14)(26) excluding such preparations [or some other amendment to Article 137 that would expressly authorize non-drug outlets sales, e.g., §6816(2) could be amended by adding a new paragraph (f)].

If the Education Department rules that such preparations are not within the meaning of §6801(14)(26), or that they are "proprietary medicines," then only the repeal of §6804-b would be necessary to authorize non-drug outlets sales. Mr. Carlino's memorandum suggests, as an alternative, the deletion in §6804-b of the words "and/or used in gynecological hygiene or treatments." However, what would remain in this section is already covered in the Education Law. Thus, from a drafting viewpoint, a repeal of the section in toto would be preferable.

It could be urged that when the Education Department approved our recommendation to transfer the substance of former Penal Law §1747-a to the Education Law, they implicitly recognized that the conduct proscribed therein was not already expressly prohibited by the Education Law, i.e., the sale of "appliances, drugs or medicinal preparations... used in gynecological hygiene or treatments." However, in fairness to the Department, I don't think this nuance was deeply considered by them. If it were, they should have suggested to us the deletion (from §1747-a) of the reference to "intended or having special utility for the prevention of venereal diseases."

The subject matter is, of course, outside the scope of criminal law as such. What follows are my personal views, unencumbered by any expertise in drug laws.

If the Education Department advises Mr. Carlino that gynecological hygiene articles are "drugs or "devices," and are not within the "proprietary medicine" exemption, then §6804-b should be repealed on grounds of redundancy. Actually, if such be the case, we should never have transferred the provision to the Education Law. If the Department is of the opinion that such articles are not "drugs" or devices," I would agree with Mr. Carlino's recommendation that §6804-b be repealed.

A close reading of this provision indicates that it is directed solely at the "prevention of venereal diseases." I cannot believe that the 1935 Legislature or the draftsman of this provision meant to deal with two distinct and unrelated subjects in a single brief provision, viz., (1) the sale of articles "intended or having special utility for the prevention of venereal diseases," and (2) the sale of articles "used in gynecological hygiene or treatments." The ambiguous conjunction "and/or" compels this interpretation.

It would be interesting to learn why this 1935 legislation was enacted. At that time Penal Law §1142 prohibited the sale by anyone (including pharmacists) of any instrument, article, drug or medicine "for the prevention of conception." It may be that contraceptive devices and preparations were being sold under the guise of "for the prevention of venereal disease." Thus, there may be a close relationship between §1747-a and §1142. The latter section was amended in 1965 (Chapter 637) to remove the absolute prohibition. A new subdivision reads, in part: "The sale or distribution of any instrument or article, or any recipe, drug or medicine for the prevention of conception, is authorized only by a duly licensed pharmacy...." In Mr. Carlino's memorandum it is stated that feminine hygiene "preparations, as well as most catamenial devices, are not...adaptable for contraceptive purposes." Query: shouldn't Mr. Carlino seek a ruling from the Education Department as to whether the State Board of Pharmacy agrees with this statement? [Penal Law §1142, as amended in 1965, will be incorporated without any change in the Public Health Law as §12-d. The 1965 Transfer Bill (ch 1031) did not, of course, pick up the 1965 amendment to §1142. That will be done in a conforming bill to be introduced at this session.]

It should be noted that Education Law Article 137 ("Pharmacy") is one of 11 articles in Title 8 ("Professional Practice"). On January 25 and 26, 1967, the Joint Legislative Committee to Revise and Simplify the Education Law (Chairman: Sen. D. Clinton Dominick III) held a public hearing in Albany to consider revision of Title 8. A notice of this public hearing read: "The scope of the Hearing is confined to comments with reference to the proposed uniform or omnibus sections of the new law and each profession's portion of the law." Has Mr. Carlino contacted this JLC?

FEB 6 1967

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2 February 1967

Hon. Richard Bartlett
10 Harlem Street
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Dear Dick:

I am enclosing a brief memo pertaining to Section 6804-b of the Education Law (formerly Section 1747-a of the Penal Law) which is self explanatory.

I would appreciate your views on this subject after you have had a chance to examine this memorandum.

Cordially,

Joseph F. Carlino

JFC:C
Enc.

Section 6804-b. of the Education Law (formerly Section 1747-a. of the Penal Law) provides as follows:

"§6804-b. Sale of certain appliances, drugs or medicinal preparations

No appliances, drugs or medicinal preparations intended or having special utility for the prevention of venereal diseases and/or used in gynecological hygiene or treatments, shall be displayed, sold or otherwise disposed of in the state of New York, except in places duly registered by the state board of pharmacy. Any person or persons, firm or corporation, or member of a firm or officer, director or employee of a corporation, who violates any of the provisions of this section is guilty of a misdemeanor."

An examination of the Jacket File of the Statute (L. 1935 c. 685) indicates that this Statute was designed primarily to restrict the sale of products intended for the treatment of venereal disease. The phrase "used in gynecological hygiene or treatments" was evidently inserted to preclude the promotion of venereal preparations as such. There are, however, a number of douche and other feminine hygiene preparations available that are perfectly safe under both the Federal and State Food and Drug Acts being sold in non-drug outlets throughout the country. These preparations, as well as most catamenial devices, are not for use in the treatment of venereal disease nor adaptable for contraceptive purposes. Accordingly, there would appear to be no valid reason to restrict their sale to drugstores as opposed to food and other non-drug outlets where the consumers' convenience would best be served.

There now exists in both the Federal and New York State Laws adequate provision to control the distribution and sale of both contraceptives and medicinal preparations designed for the treatment of venereal disease. Accordingly, there appears to be no reason to continue these criminal sanctions in the New York Law. Under these circumstances, it is proposed

that this Section may be deleted in its entirety without any jeopardy to the public health. Although this approach is to be most desired, in the alternative it is suggested that the same result could be achieved by amending the Section to delete the words "and/or used in gynecological hygiene or treatments".