

IN THE MATTER OF	*	BEFORE THE
X-GEN PHARMACEUTICALS	*	MARYLAND STATE
Respondent-Distributor	*	BOARD OF PHARMACY
Permit Number: D02937	*	Case Number: PI-13-059/13-459

* * * * *

CONSENT ORDER

On August 21, 2013, the Maryland State Board of Pharmacy (the "Board") charged X-GEN PHARMACEUTICALS (the "Respondent-Distributor"), Permit Number D02937, under the Maryland Pharmacy Act (the "Act"), Md. Health Occ. Code Ann. ("H.O.") §§ 12-101 *et seq.* (2009 Repl.Vol. & 2012 Supp.).

The pertinent provisions of the Act are as follow:

H.O. § 12-6C-03. Permit required.

- (a) *Wholesale Distributor.* – A wholesale distributor shall hold a permit issued by the Board before the wholesale distributor engages in wholesale distribution in the State.

H.O. § 12-6C-11. Violations; penalties.

- (a) *Fine.* – (1) If a person knowingly violates any provision of this subtitle or any regulation adopted under this subtitle, the Board may impose a fine not to exceed \$500,000.

The Board further charges the Respondent-Distributor with violating the following provision of the Boards regulations – Code Md. Regs. § 10, tit. 34.22.00 *et. seq.* – Licensing of Wholesale Prescription Drug or Device Distributors:

10.34.22.05 – Violations and Penalties.

- A. After a hearing held under Health Occupations Article, § 12-601, Annotated Code of Maryland, the Board may deny, suspend, revoke, or place on probation a permit holder, reprimand a permit holder, or impose a fine if the permit holder:

...

- (4) Is disciplined by a licensing or disciplinary authority of any state or country, or disciplined by a court of any state or country, for an act that would constitute a ground for Board action against a wholesale distributor permit holder under § A or B of this regulation[.]¹

FINDINGS OF FACT

1. The Respondent-Distributor is located in Horseheads, New York.
2. The Respondent-Distributor was initially licensed as a wholesale distributor in the State of Maryland on December 8, 2009. The Respondent-Distributor's permit is currently active and is scheduled to expire on May 31, 2015. The Board received information that prior to the issuance of the Respondent-Distributor's permit, the Respondent-Distributor operated as a wholesale distributor in Maryland.
3. The Board subsequently initiated an investigation.
4. The Board's investigation revealed that from January through December 2008, the Respondent-Distributor shipped drugs without a Maryland permit primarily to a wholesale distributor, but also to several hospitals and pharmacies located in Maryland. The drugs included, but were not limited to, antibiotics, anti-bacterials, antifungals and steroids.
5. In 2008, the value of the drugs the Respondent-Distributor sold to these entities is approximately \$1,674, 816.
6. From January through November 2009, the Respondent-Distributor shipped drugs without a Maryland permit to a wholesale distributor, several hospitals and pharmacies located in Maryland. The drugs included but were not limited to antibiotics, anti-bacterials, antifungals and

¹ Section A of the regulation lists prohibited activities; Section B excepts one activity as prohibited.

steroids.

7. In 2009, the value of the drugs the Respondent-Distributor sold to these entities is approximately \$1,496,312.
8. The Respondent-Distributor has been disciplined by pharmacy boards in several other states for distributing prescription drugs in those states when not registered to do so:
 - a. Colorado – effective February 5, 2009, the Respondent-Distributor was issued a Cease and Desist Order for distributing prescription drugs in Colorado in December 2008 in the absence of registration. Effective February 24, 2009, the Respondent-Distributor entered into a Final Agency Order under the terms of which it agreed to pay a fine of \$5,750;
 - b. Maine – Effective July 13, 2011, the Respondent-Distributor entered into a Consent Order in which it admitted that it had practiced as a wholesale pharmacy in Maine without being licensed by the Maine Board of Pharmacy. Specifically, from 2006 through 2009, the Respondent-Distributor had shipped 81 prescriptions into Maine without being licensed to do so. The Respondent-Distributor agreed to pay a civil penalty of \$1,580;
 - c. Illinois – effective November 29, 2011, the Illinois Board reprimanded the Respondent-Distributor based on

Maine's discipline for unlicensed wholesale drug distribution;

d. Montana – on February 7, 2012, the Montana Board filed a "Notice of Board Action and Opportunity for Hearing" against the Respondent-Distributor, alleging that in 2007, 2008 and 2009, the Respondent-Distributor had shipped several units of drugs to Montana prior to being licensed in that state. Effective April 17, 2012, the Montana Board issued a Final Order of Default in which it noted that the Respondent-Distributor had not requested a hearing in the matter and ordered the Respondent-Distributor to pay an administrative fine of \$3,000.

CONCLUSIONS OF LAW

Based on the foregoing Findings of Fact, the Board concludes that the Respondent-Distributor violated H.O. § 12-6C-03(a).

ORDER

Based on the foregoing Findings of Fact and Conclusions of Law, it is by a majority of the quorum of the Board considering this case:

ORDERED that the Respondent-Distributor is reprimanded; and it is further

ORDERED that within 90 days of the effective date of the Consent Order, the Respondent-Distributor shall pay a monetary fine of \$30,000, to be paid in full to the Board by certified or bank guaranteed check made payable to the Maryland State Board of Pharmacy; and it is further

ORDERED that the Respondent-Distributor shall comply with the Maryland Pharmacy Act and all laws, statutes and regulations pertaining to the practice of pharmacy; and it is further

ORDERED that the Respondent-Distributor's failure to comply with any of the conditions of this Consent Order shall be considered a violation of this Consent Order; and it is further

ORDERED that if the Respondent-Distributor violates any of the conditions of this Consent Order, the Board, in its discretion, after notice and an opportunity for a show cause hearing before the Board, may impose any other disciplinary sanction for which the Board may have imposed, including an additional monetary fine; and it is further

ORDERED that the effective date of this Consent Order is that date that it is signed by the Board; and it is further

ORDERED that this document constitutes a formal disciplinary action of the Maryland Board of Pharmacy and is therefore a public document for purposes of public disclosure, pursuant to Md. State Govt Code Ann. §§ 10-611 *et seq.* (Repl.Vol. 2009 & Supp. 2012).

Date

10/16/2013


Lenna Israbian-Jamgochian, Pharm.D.
President
Maryland Board of Pharmacy

**CONSENT OF SUSAN BADIA, PRESIDENT OF
X-GEN PHARMACEUTICALS**

I, Susan Badia, President of X-Gen Pharmaceuticals, acknowledge that I am represented by counsel and have consulted with counsel before entering this Consent Order. By this Consent and for the purpose of resolving the issues raised by the Board, I agree and accept to be bound by the foregoing Consent Order and its conditions.

I acknowledge the validity of this Consent Order as if entered into after the conclusion of a formal evidentiary hearing in which I would have had the right to counsel, to confront witnesses, to give testimony, to call witnesses on my own behalf, and to all other substantive and procedural protections provided by the law. I agree to forego my opportunity to challenge these allegations. I acknowledge the legal authority and jurisdiction of the Board to initiate these proceedings and to issue and enforce this Consent Order. I affirm that I am waiving my right to appeal any adverse ruling of the Board that I might have filed after any such hearing.

I sign this Consent Order after having an opportunity to consult with counsel, voluntarily and without reservation, and I fully understand and comprehend the language, meaning and terms of the Consent Order.

09/16/2013
Date

Susan E. Badia
Susan Badia, President
X-Gen Pharmaceuticals
Respondent-Distributor

Reviewed by:

J. B. [Signature]
Attorney for Respondent-Distributor

STATE OF New York

CITY/COUNTY OF Suffolk

I HEREBY CERTIFY that on this 16 day of September 2013, before me, a Notary Public of the foregoing State and City/County personally appeared Susan Badia, President, X-Gen Pharmaceuticals, and made oath in due form of law that signing the foregoing Consent Order was her voluntary act and deed.

AS WITNESSETH my hand and notarial seal.

John R. Heven
Notary Public

My Commission expires: 6-15-15

JOHN R HEVEN
Notary Public, State of New York
No. 01HE5012085
Qualified In Nassau County
Commission Expires June 15, 2015