APPENDIX

New Jersey's Flood Hazard Area Control Act Rules Changes on Adoption and Concurrent Proposal

New Jersey Department of Environmental Protection
Division of Land Use Regulation

May 16, 2016

FHACA Rulemaking

- Comprehensive proposal was published 6/1/15 with a 60-day public comment period
- NJDEP received 875 unique comments from 845 commenters
- Comments brought to light issues that had not previously been considered
- Amendments are being made on adoption to:
  - Clarify NJDEP's intent with the rulemaking
  - Ensure continued protection of headwaters
  - Ensure that riparian zone disturbance is permitted only where unavoidable, beneficial, and/or *de minimis*

/x

Changes on Adoption

Headwater protection

- Headwaters are naturally-occurring sources of a surface water, such as a spring or where surface waters coalesce into a discernible linear feature.
- Clarifications were proposed to "regulated waters" at N.J.A.C. 7:13-2.2 and "tributaries" at N.J.A.C. 7:13-4.1.
- Proposal was not intended to change the waters regulated under the FHACA Rules but were perceived by many commenters as doing so.
- These proposed changes are **not adopted** in order to ensure headwater protections are unchanged.

Changes on Adoption

Headwater protection (continued)

- Piped waters that drain less than 50 acres were proposed to be deregulated.
- Commenters noted that this would allow stormwater discharges directly into piped waters and thereby bypass important water quality controls.
- These proposed changes are **not adopted** in order to ensure that existing water quality requirements are maintained.

2x

Changes on Adoption

Riparian zone disturbance

- These proposed provisions are **not adopted** to ensure that riparian zone disturbance is not excessive and to prevent unwarranted development along C1 waters:
  - Extra ¼ acre of disturbance to "actively disturbed areas" in addition to amounts allowed under Table 11.2 for an IP at N.J.A.C. 7:13-11.2(f)1.
  - Disturbance of ¼ acre of riparian zone vegetation under "other" category at N.J.A.C. 7:13-11.2(y).
  - Proposed permit-by-rule for artificial turf athletic fields at N.J.A.C. 7:13-7.26.

Changes on Adoption

Category One waters

- A new provision is being added to the SWM Rules to clarify that protections to Category One waters formerly provided by SWRPAs are not being removed, but are being combined with the 300-foot riparian zone requirements in the FHACA Rules.
- This provision will help ensure our continued consistency with the federal Clean Water Act and the State's Water Pollution Control Act.

3x

Concurrent Proposal

- A review of the public comments that were received revealed areas in which adopted rules could be clarified and additional protections instituted.
- Amendments on adoption are limited by the Administrative Procedures Act and so were included in a new rulemaking that would amend the newly adopted FHACA Rules.
- Not intended to fix adopted rule but rather to augment water quality protections and to address other issues raised by commenters.
- To be published in same N.J. Register as adoption.

Concurrent Proposal

Added level of protection for work within 150 feet of a Category One water or tributary:

- Permits-by-rule, general permits-by-certification, and general permits are amended to ensure that work within inner half of 300-ft riparian zone is avoided or limited to *de minimis* impacts (such as small disturbances to existing lawn or landscaped areas).
- With limited exceptions, activities authorized under these permits cannot be a "major development" under the SWM Rules and therefore would not have triggered the SWRPA.

Concurrent Proposal

Added level of protection for work within 150 feet of a Category One water or tributary:

- Under individual permits, applicants are required to demonstrate an additional level of justification in order to disturb vegetation within inner half of 300-ft riparian zone.
- Mitigation is required for all disturbance within a 300-ft riparian zone, no matter how small the impact, except for certain activities exempt from SWRPA standards.
- This is more protective than existing SWRPA, which applies only to "major developments."

Concurrent Proposal

- **Aligns lowest floor and flood-proofing requirements for buildings with NJ Uniform Construction Code and National Flood Insurance Program requirements**
  - Incorporates UCC & FEMA's V-zone construction standards
  - Incorporates UCC's new Coastal A-zone construction standards
  - Limits flood-proofing to techniques and uses permitted under UCC
- **Facilitates environmentally beneficial projects performed by USDA Natural Resource Conservation Service and US Fish & Wildlife Service**
  - In response to comments by NRCS and USF&WS

5x

STATEMENT

PhRMA
RESEARCH • PROGRESS • HOPE

In Opposition to New Jersey S.580 (Doherty)

May 13, 2016

Position: The Pharmaceutical Research and Manufacturers of America (PhRMA) opposes S.580 which seeks to create the New Jersey Water Supply and Pharmaceutical Product Study Commission to study and investigate the potential risks associated with pharmaceuticals in the water supply. This legislation is unnecessary as scientific analysis has already determined that the trace amounts of pharmaceuticals in the environment are not a risk to human health.

Pharmaceuticals are generally measured in the environment in parts per trillion (PPT). These trace amounts are equivalent to a sugar cube in four Olympic-sized pools. Studies conducted to date, published in peer-reviewed journals, which include work on sensitive subpopulations, suggest that there is no appreciable risk to human health from the presence of the very small quantities of pharmaceuticals detected in the environment.[1][2][3][4]

Pharmaceuticals in the environment

Due to how our bodies metabolize the medicine we take, some trace amounts of pharmaceuticals may still be found in surface waters. When a drug passes through the body without being fully metabolized, trace amounts of the medication enter the wastewater treatment system and find their way into surface waters. The Food and Drug Administration (FDA) finds that "the main way drug residues enter water systems is by people taking medicines and then naturally passing them through their bodies…many drugs are not completely absorbed or metabolized by the body and can enter the environment after passing through wastewater treatment plants. While FDA and the Environmental Protection Agency take the concerns of flushing certain medicines in the environment seriously, there has been no indication of environmental effects due to flushing."[5]

Relevant Studies

Questions about the safety of drinking water have been addressed over several years by authors from academia, government, non-government sector and the pharmaceutical industry. Chemicals used as active pharmaceutical ingredients (APIs) are among the most thoroughly studied substances in the world for their effects on human health. To date, no published investigation has found that exposure to these detectable residues creates any significant risk to human health.[6][7][8][9]

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[1] Christensen, F.M. *Pharmaceuticals in the environment – A Human Risk?,* Reg. Toxicol. & Pharmacol., 28, 212-221. (1998)
[2] Schwab, et al. *Human pharmaceuticals in US surface waters: A human health risk assessment.* Regulatory Toxicology and Pharmacology, Volume 42, Issue 3, *Pages 296-312* (August, 2005)
[3] Webb, et al. *Indirect human exposure to pharmaceuticals via drinking water,* Toxicology Letters, 142, 157-167. (2003)
[4] Mons, M.N., (2003) *Pharmaceuticals and drinking water supply in the Netherlands*, Kiwa N.V. Water Research.
[5] Dr. Raanan Bloom, Ph.D. "How to Dispose of Unused Medicines" Food and Drug Administration http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm101653.htm; 6/04/2015
[6] Christensen, F.M. *Pharmaceuticals in the environment – A Human Risk?,* Reg. Toxicol. & Pharmacol., 28, 212-221. (1998)
[7] Schwab, et al. Human pharmaceuticals in US surface waters: A human health risk assessment. Regulatory Toxicology and Pharmacology, Volume 42, Issue 3, Pages 296-312 (August, 2005)
[8] Webb, et al. *Indirect human exposure to pharmaceuticals via drinking water,* Toxicology Letters, 142, 157-167. (2003)
[9] Mons, M.N., (2003) *Pharmaceuticals and drinking water supply in the Netherlands*, Kiwa N.V. Water Research.

6x

In "Effects of Human Pharmaceuticals on Aquatic Life: Next Steps," this peer-reviewed publication finds that although some active pharmaceutical ingredients have been measured in drinking water, the scientific consensus is that pharmaceuticals at the low levels detected in the environment do not pose an appreciable risk to human health. It is important to remember that all pharmaceuticals go through the Food and Drug Administration's rigorous testing for human safety, and that standards for potential environmental impact are considered as part of the FDA application.[10]

The peer-reviewed report "Landfill Disposal of Unused Medicines Reduces Surface Water Releases" finds that the disposal of unused medications in municipal solid waste landfills effectively eliminates the unused medicine contribution of active pharmaceutical ingredients to surface waters and that more than 99.9% of what is disposed of in landfills are permanently retained (e.g., medicines are not leaching out of landfills).[11] This is important to note because the New Jersey Department of Environmental Protection has "Guidelines for Proper Disposal of Household Medication" which encourages disposing of unwanted and expired prescriptions and over-the-counter medications in the trash. The report confirms that landfills are a safe disposal option for unused medicines.

Promoting Sustainability in Manufacturing

The pharmaceutical industry collaborates with various local, state, and federal agencies to understand and reduce the environmental impact of the research and manufacturing process for new medicines. The member companies of PhRMA comply with extensive federal, state, and local regulations governing the pharmaceutical manufacturing process, including all guidelines addressing the pre-treatment and testing of wastewater streams. As part of our development and manufacturing processes, our members research the impact its chemical compounds may have on the environment.

In addition to ongoing collaboration with government agencies, many individual companies are also employing "green chemistry" principles in the design, development, and manufacture of medicines. Many of our member companies have received LEED awards for their innovative efforts in green building and construction, energy conservation and green chemistry.

As peer-reviewed studies indicate little risk to human health posed by such insignificant amounts of pharmaceuticals in the environment and no studies have published studies to date showing any harm to people from these amounts, PhRMA respectfully asks that New Jersey legislators oppose S.580.

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10 Effects of Human Pharmaceuticals on Aquatic Life: Next Steps: Virginia Cunnigham, GlaxoSmithKline; Mary Buzby Merck and Co., Inc.; Thomas Hutchinson, AstraZeneca; Frank Mastrocco Pfizer, Inc.; Neil Parke, Eli Lilly and Co.; Nicholas Roden, Schering-Plough Corp. in the *Environmental Science & Technology Journal* published by the American Chemical Society

[11] Lial Tischler, Mary Buzby, Douglas Finan, and Virginia L Cunningham "Landfill Disposal of Unused Medicines Reduces Surface Water Releases" *Integrated Environmental Assessment and Management Journal*