

FOR IMMEDIATE RELEASE May 15, 2023	Contact: Joe Gitchell CEO Pinney Associates, Inc. jgitchell@pinneyassociates.com
---------------------------------------	--

**PINNEY ASSOCIATES, INC., ANNOUNCES PROMOTIONS OF
KEY MEMBERS TO LEADERSHIP TEAM**

Bethesda, Maryland – Pinney Associates, whose expert team anticipates pharmaceutical and consumer healthcare companies’ scientific and policy challenges and guides them toward regulatory and marketplace success, is pleased to announce its new leadership team.

Joe Gitchell recently assumed the role of CEO, Lucy Owen is our new President, Judy Ashworth has been promoted to Senior Vice President, and Robyn Gougelet has been promoted to Vice President, Health Policy and Regulatory Strategy.

In their new roles, they provide strategic advice and tactical support to help clients reduce regulatory risk and achieve regulatory approval across our four practice areas. We help clients switch prescription medications to over-the-counter status, support the clinical and regulatory development of central nervous system (CNS)-active medications, advise on the development and commercialization of dietary ingredients and supplements, and advance research and policies to minimize the death and disease caused by smoking cigarettes.

Lucy Owen, in her 25 years at Pinney Associates, has made significant contributions to public health by guiding clients through the complex and dynamic Rx-to-OTC switch regulatory process. Lucy specializes in developing and executing science-based regulatory strategies that help our clients to:

- Identify and address the issues raised by switches and meet FDA’s switch requirements;
- Develop research-based OTC labeling for switch products;
- Design behavioral and other studies to support switches;
- Build the individual and public health focused benefit-risk case for switches; and
- Prepare for FDA interactions, regulatory submissions, and advisory committee meetings.

Lucy and her Pinney Associates team are providing critical support to HRA Pharma / Perrigo who submitted an application to the Food and Drug Administration (FDA) for the Rx-to-OTC switch of OPILL® in July of 2022. OPILL® would be the first oral contraceptive approved for sale in the U.S. without a prescription. On May 10, 2023, the Joint Meeting of the FDA’s Nonprescription Drugs Advisory Committee and the Obstetrics, Reproductive and Urologic Drugs Advisory Committee Meeting voted unanimously (17-0 with no abstentions) that the benefits of making OPILL® available for over-the-counter (OTC) use outweigh the risks. HRA Pharma / Perrigo expects the agency could make a final decision on approval of the product by the end of the summer.

Judy Ashworth, MD, who has been with Pinney Associates since 2018, guides the clinical development of CNS-active drugs in a challenging and rapidly evolving regulatory environment.

Judy collaborates with clients developing CNS-active drugs, from traditional pharmaceuticals to psychedelics and cannabinoids, for neurologic and psychiatric indications.

She specializes in:

- Clinical development plans and trial design;
- Regulatory strategy;
- Target product profile development;
- Indication selection; and
- Business development support for partnering and fundraising.

Robyn Gougelet, who has been with the firm for eight years, has been a key member of our tobacco harm reduction team. Robyn has played a critical and central role in advising clients on public health legislative and regulatory policy efforts, as well as regulatory submissions to FDA.

"We are thrilled to have promoted these talented individuals to our leadership team," said John Pinney, Founder and Chair of Pinney Associates. "Each of them brings unique skills and experiences that will help us continue to deliver exceptional value to our clients and better public health."

"For over thirty years, Pinney Associates has worked hand-in-hand with our clients to overcome their regulatory and policy challenges by identifying root causes and developing innovative solutions based on medical and behavioral science and public health. We look forward to future collaborations with clients to increase access to products that advance individual and public health," asserted CEO Joe Gitchell.

Pinney Associates is a science-based health consulting firm with unique resources and broad experience in scientific, medical, public health, regulatory and commercial aspects of prescription and consumer healthcare products. Pinney Associates' scientists include internationally respected leaders at the intersection of public health, behavioral science, and medicines. We help our clients to manage issues and enhance the scientific and policy environments to gain regulatory approval of, and maximize acceptance of, pharmaceutical and consumer healthcare products. Pinney Associates' experts have extensive expertise and experience in medicines with abuse potential, Rx-to-OTC switch and consumer healthcare products.

For more information, please visit the Pinney Associates website, at www.pinneyassociates.com.