Sen. Siobhan S. Dunnavant
Pocahontas Building
Room No: E613
Senate of Virginia
P. O. Box 396
Richmond, VA 23218

January 25, 2020

Dear Senator Dunnavant,

We represent the Virginia Gastroenterological Society, a community of over 150 physicians and allied health professionals serving the Commonwealth. We appreciate your commitment to supporting the practice of medicine in Virginia through your many legislative initiatives.

In our work with the Medical Society of Virginia (MSV) Specialty Leadership group, it has come to our attention that Senate Bill No. 1026[1], published January 16 and sponsored by both you and Sen. Pillion, a dentist, includes language concerning pharmacists' scope of practice that we believe violates accepted standards of care.

As a general policy, the authorization of pharmacists to independently "prescribe, dispense, and administer" drugs and devices, including vaccines, supplements, tuberculin testing agents, injectable contraceptives, antivirals, antibacterials, and HIV prophylaxis agents, would seem both unnecessary and potentially dangerous. We wish to focus, however, on the one test specified in the bill that falls within our area of expertise: *Helicobacter pylori* infection.

SB 1026[1] includes the following provision:

§ 54.1-3303.1. Prescribing, dispensing, and administering of controlled substances by pharmacists.

A. Notwithstanding the provisions of § 54.1-3303, a pharmacist may prescribe, dispense, and administer the following drugs and devices in accordance with a statewide protocol developed by the Board in consultation with the Board of Medicine and set forth in regulations of the Board:
    8. Drugs or devices for the treatment of diseases or conditions caused by infection with influenza virus, **Helicobacter pylori bacteria,** or group A Streptococcus bacteria or a urinary tract

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infection if such infection is confirmed by a positive result on an approved test administered by the pharmacist. If an approved test administered by the pharmacist is negative, the pharmacist shall not prescribe, dispense, or administer such drugs or devices and shall refer the patient to a health care provider for diagnosis and treatment;

The management of *H. pylori* has changed since its original discovery in 1983, evolving from a broad "test and treat" strategy for patients with a variety of gastrointestinal symptoms to a targeted approach offering testing to only those high-risk patients who would be candidates for eradication, if positive.

Who are those high-risk patients? According to a recent American College of Gastroenterology (ACG) clinical guideline summary[2], all patients with documented gastric or duodenal ulcer should be tested for *H. pylori* at the time of diagnosis. Since pharmacists will have no ability to diagnose ulcer, this is not applicable. Additional clinical indications with a strong recommendation, as shown in Table 1, include history of peptic ulcer disease, gastric MALT lymphoma, and early gastric cancer. Similarly, pharmacists will not have access to a medical record proving the presence or absence of these conditions, so treatment without participation by the diagnosing physician is not reasonable.

Table 1. Indications for *Helicobacter pylori* testing and treatment

• All patients with PUD (strong recommendation; quality of evidence: high)
• History of PUD (strong recommendation; quality of evidence: high)
• Gastric MALT lymphoma (strong recommendation; quality of evidence: low)
• Endoscopic resection of early gastric cancer (strong recommendation; quality of evidence: low)
• Uninvestigated dyspepsia under the age of 60 years and without alarm features (conditional recommendation; quality of evidence: high for efficacy and low for age threshold)
• Functional dyspepsia (strong recommendation; quality of evidence: high)
• Patients taking long-term, low-dose aspirin (conditional recommendation; quality of evidence: moderate)
• Patients initiating chronic treatment with a nonsteroidal anti-inflammatory drug (conditional recommendation; quality of evidence: low)
• Patients with unexplained iron deficiency anemia despite an appropriate evaluation (conditional recommendation; quality of evidence: low)
• Adults with idiopathic thrombocytopenic purpura (conditional recommendation; quality of evidence: very low)
MALT, mucosa-associated lymphoid tissue; PUD, peptic ulcer disease. Reprinted with permission (3).

Source: Chey, WD (Ref. 2)

With regard to symptoms, the ACG guideline summary indicates a "strong recommendation" for testing and treating patients with functional dyspepsia, a nonspecific chronic disorder of epigastric complaints, early satiety, and nausea that has a wide differential diagnosis. No other medical conditions shown in Table 1 include a "strong recommendation" for testing and treating. In fact, the full clinical guideline on *H. pylori* published in 2017 warns against testing patients with gastroesophageal reflux disease (GERD) because the effects of eradication in this setting

are uncertain.[3] Pharmacists do not have the clinical expertise to distinguish chronic dyspepsia from GERD.

The tests that pharmacists would use to diagnose *H. pylori* are not specified in SB 1026. Presumably, serology would be the test of choice given the ease of obtaining a blood sample in a pharmacy. However, serologic testing only indicates prior exposure to the bacterium; it does not prove active infection.[3] Further, in areas of relatively low prevalence, the rate of false positive *H. pylori* serology is high[4]; if treatment were offered to all of these patients, unnecessary and potentially harmful antibiotic therapy would be provided by Virginia pharmacists without physician involvement. Serologic testing has been largely abandoned in clinical practice. In lieu of serology, gastroenterologists rely upon urea breath testing and stool studies to diagnose active *H. pylori* infection; these tests might not be practical in most local pharmacies. This would render diagnosis of active *H. pylori* infection by pharmacists a futile exercise.

In addition to the challenges pharmacists would face deciding whom and how to test, the treatment of *H. pylori* remains complex due to regional differences in antibiotic drug resistance. Considerations such as previous exposure to antibiotics, drug intolerances, and risk of *C. difficile* must all be taken into account when treating *H. pylori*.[3] Indiscriminate use of antibiotics without a proper history from a trained clinician or confirmation of active infection should be discouraged.

Lastly, the ACG clinical guideline advocates testing for bacterial eradication four weeks after completion of therapy with one of several diagnostic methods capable of determining active infection: urea breath test, stool antigen test, or biopsy.[3] None of these measures are practical for use or even possible in a pharmacy setting.

We urge you to reconsider the inclusion of *H. pylori* in SB 1026. We further request that you and co-sponsor Sen. Pillion consider the broader concerns that have been raised by the MSV regarding this proposed legislation governing pharmacists' scope of practice.

We are happy to provide additional supportive information at your request.

Respectfully,

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References

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