JM is a 35yo female with a history of recurrent migraines.

As instructed by her neurologist, she takes ibuprofen for minor headaches and reaches for her Imitrex (sumatriptan) when she feels the building aura and temporal throbbing that signals a true migraine. Every 6 months or so, even two doses of sumatriptan fail to control her severe headache, at which time her husband drives her to the emergency department, her head buried in her knees, for rescue medication. By the time she arrives, she is sometimes vomiting from the intensity of her pain.

Typically, an IV is placed, and she receives IV ketorolac and IV prochlorperazine. She then rests in a dark room, and within 20 minutes, the pain and nausea subside. Within 2 hours, she is home, feeling better. This is not an unexpected outcome: IV administration of prochlorperazine is first line treatment for migraine in the emergency department according to the American Academy of Neurology 2000 migraine guidelines.

The other week, JM was unable to get her usual medications, due to a nationwide shortage of IV prochlorperazine. Could she take the medication by mouth? It was still available PO, the nurse offered. Looking at JM gagging into her plastic emesis bag, we determined the answer was definitely no. Now what?

And so the nationwide issue of drug shortages, pharmaceutical company disclosures, and FDA (Federal Food and Drug Administration) oversight comes to life for another patient.

The issue of drug shortages is finally receiving attention in Congress, with two active House and Senate bills (H.R. 2445/S. 296) striving to add enforcement to an October executive order that pushed to condemn drug stockpiling and improve drug shortage reporting. A bipartisan Senate working group is investigating root causes of the drug shortages, and a Utah senator is drafting another bill to add financial incentives to proposed enforcement. The New England Journal of Medicine (NEJM) published a strong call to action for legislators and pharmaceutical companies to rise to public obligation and meet demand of critical generic drugs.

As physicians, we should care. As emergency physicians, we must care. AAEM/RSA’s Advocacy Committee is working to show why this issue needs to be on our radar: drug shortages don’t just affect patients—they now affect OUR patients and OUR treatment choices. In order to advocate for patients like JM, we must familiarize ourselves with a growing list of unavailable medications and the surrounding issues.

Between 2009 and 2010, the list of drugs on shortage grew from 157 to 178 and currently exceeds 275 FDA approved therapies. Originally comprised of mostly anesthetic and oncologic drugs, the list is creeping into our domain: black widow spider venom, calcium chloride, etomidate, fentanyl, furosemide, ketorolac, labetalol, ondansetron, phenytoin, prochlorperazine and rabies immunoglobulin. The majority of the medications are for IV use, and the suspicion is that the cost to produce these generic drugs outweighs the negotiated reimbursement by most hospital or insurance systems—in particular, Medicare.

What is the impact of these shortages? Few of these medications have adequate alternatives by function or cost. Change is also prone to error. This crisis means worse outcomes for our patients, increased risk of medical error, increased costs for caregivers and taxpayers, and a general undermining of confidence in our country’s health care system. According to research by Premier, drug shortages could cost U.S. hospitals at least $415 million annually. The NEJM cited expert opinion that federal government pricing and rebate programs are a significant contributing factor to the current drug shortage crisis. Many U.S. pharmaceutical companies earn more by selling their generic drugs abroad.

What’s been done? President Obama’s executive order on “Reducing Prescription Drug Shortages” heightened reporting requirements for potential manufacturing shortages, in particular for “critical drugs” - those that are life supporting or life sustaining, or that prevent debilitating disease. The order also instructed the FDA to accelerate reviews of new applicants seeking to enter the generic market and to inform the Justice Department about possible collusion or price gouging related to the shortages.

House bill H.R. 2445 and Senate bill S. 296 are now on the table to further strengthen the executive order. They propose a formal six month notice for manufacturing shortages of “critical drugs” and heighten enforcement by empowering the FDA to expand its Drug Shortage Program (DSP). Currently, only three staffers within the FDA DSP handle drug shortages for the entire country, and there is no mandatory reporting.

In the works is a bill by Senator Orrin Hatch (R-Utah) proposing financial incentives for manufacturers to avoid letting drug shortages develop or create contingency plans for when they do. In his December 7 address to Congress, the Senator said he is “working on a solution that will continue to improve coordination between manufacturers and the government, but that also addresses some of the federal price control and rebate structures that prevent the true costs of bringing these important medicines to patients.” Options include making drugs on the FDA’s Drug Shortage Program temporarily exempt from the heavily discounted Drug Pricing Program.

In the same vein, a recent New York Times piece by oncologist and former White House adviser Emanuel Ezekiel proposed that such relaxation of FDA price controls could promise a long-term solution by empowering supply and demand. He writes (regarding cancer drugs), “[p]rice once a drug becomes generic, Medicare should stop paying, and it should be covered by a private pharmacy plan. That continued on page 14
way prices can better reflect the market, and market incentives can work to prevent shortages.\textsuperscript{7}

While that may be a viable long-term solution, measures like H.R. 2445 and S. 296 may help patients like JM now. Along with supporting such legislation, we should aim to help to shape it. Of particular significance are the yet-undefined “critical drugs” to be included in Senator Hatch’s bill – and AAEM/RSA is on board to help craft the definition to include emergency-relevant drugs.

How do we help? The definition of “critical drugs” is currently determined by the “Regulatory and Legislative Recommendations from the Drug Shortages Summit Steering Group.” Historically, this group includes the following associations (because their medications were often listed): American Society of Health-System Pharmacists, the American Hospital Association, the American Society of Anesthesiologists, the American Society of Clinical Oncology, and the Institute for Safe Medication Practices. AAEM/RSA is looking to add our support, because the national shortages are increasingly affecting ER docs, and we believe that our patients’ interests need be included in determining what drugs are counted as “critical drugs.”

We are on Capitol Hill to introduce our thoughts on critical drugs: what we rely on for sick and dying patients, what we reach for to treat pain safely, and what we need to meet joint commission measures and medical standards of care. Only by communicating with our legislators can we ensure that our interests and the interests of our patients are clearly represented.

For questions or further resources, remember that RSA is “With you all the way!”

Dr. Ross welcomes your email correspondence at teresa.ross@medstarnet.

References: