

Dear Patient:

In this issue, we explore the newly revised blood pressure guidelines, and why diet and lifestyle modifications will assume even more importance in managing hypertension. We also address the reasons behind the rise in generic drug prescriptions, and why you need not be concerned about using them instead of a more familiar brand-name version. Finally, we take a look at a problem that's affecting the health of our country – food waste – and how we can all make a difference with just a few thoughtful changes in the way we shop and prepare food.



Enjoy our latest healthy read,
Michael D. Mignoli, MD, FACP

A New Normal: How Will the Revised Blood Pressure Guidelines Affect You?

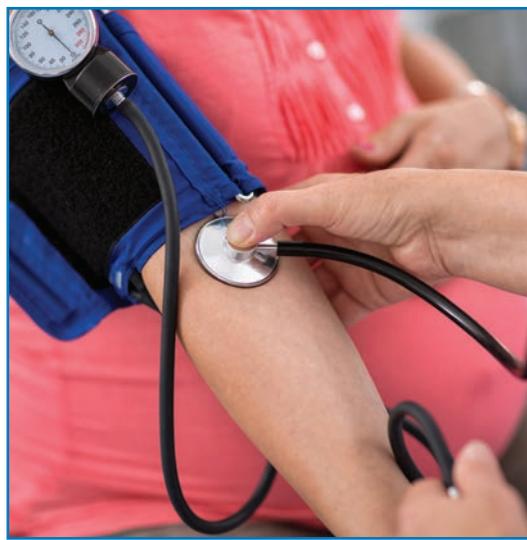
When new guidelines for identifying high blood pressure were published late last year, placing virtually half the U.S. adult population in the hypertension category, patients were understandably concerned. However, it is reassuring to note that this update to high blood pressure guidelines - the first since 2003 - simply pointed out some inescapable truths:

- ◆ High blood pressure should be treated earlier with lifestyle changes, and in some patients, with medication, at 130 – 139 mm Hg/80-89 mm Hg rather than the previous 140/90. Lowering the definition of high blood pressure and issuing guidelines for earlier intervention will help people address the potentially deadly condition at a point when complications can be avoided.
- ◆ While about 14 percent more people will be diagnosed with high blood pressure and counseled about lifestyle changes, it will result in only a small increase in patients who need medication.
- ◆ Diet and lifestyle changes are the preferred, and powerful, ways to literally move the needle on the blood pressure reading, as well as prevent hypertension from occurring in people with normal blood pressure. **“Lifestyle modification is the cornerstone of the treatment of hypertension, and we expect that these guidelines will cause our society to really pay attention much more to lifestyle recommendations,”** said Robert M. Carey, MD, University of Virginia School of Medicine, who participated in the writing of the guidelines.

Paul K. Whelton, M.D., lead author, noted the dangers of blood pressure levels between 130-139/80-89 mm Hg not highlighted previously. “You’ve already doubled your risk of cardiovascular complications compared to those with a normal level of blood pressure,” he said. “We want to be straight with people – if you already have a doubling of risk, you need to know about it. It doesn’t mean you need medication, but it’s a yellow light that you need to be lowering your blood pressure, mainly with non-drug approaches. We think Stage 1 hypertension is the appropriate term, and that will capture the risk for adults and clinicians much better.”

The guidelines also stress the importance of home blood pressure monitoring using validated devices and raising awareness of what is known as “white-coat hypertension,” a common phenomenon in which patients register elevated blood pressure readings only in a medical setting but not in everyday life. Home readings can also identify “masked hypertension,” when pressure is normal in a medical setting but elevated at home, which may require treatment with lifestyle and possibly medications.

“People with white-coat hypertension do not seem to have the same elevation in risk as someone with



true sustained high blood pressure,” Whelton said. However, he noted: “Masked hypertension is more sinister and very important to recognize because these people seem to have a similar risk as those with sustained high blood pressure.”

Lifestyle changes recommended are sound if unsurprising: a diet rich in fruits, vegetables and whole grains, with minimal amounts of sodium and unhealthy fats, coupled with physical activity. For the elevated blood pressure category, specific non-drug interventions recommended are:

- ◆ A diet high in fruits and vegetables, such as Dietary Approaches to Stop Hypertension (DASH) diet

Did You Know?

21: Number of scientists and health experts who developed the new blood pressure guidelines, based on a three year review and data from almost 1,000 published studies.

46%: Percentage of adults now identified with elevated blood pressure, up from 32% under old guidelines.

- ◆ Reduce sodium to less than 1500 mg/day
- ◆ Physical activity at a minimum of 30 minutes of exercise 3 times weekly, ideally 5
- ◆ Limit alcohol intake to two drinks or less per day for men and one or less for women
- ◆ Quit smoking

According to Harvard Health, simply changing what you eat can bring down systolic blood pressure by as much as 11 points, and each additional healthy habit you adopt can bring it down another four to five points.

Please note: Not all medical organizations have reached a consensus on these revised definitions of hypertension. The best course of action is always to consult with your physician on an individualized approach for managing your blood pressure.

The Lowdown

- ◆ Normal blood pressure is under 120/80 mm Hg, whereas before, normal was under 140/90.
- ◆ Now, elevated blood pressure (without a diagnosis of hypertension) is systolic (the top number) blood pressure between 120 and 129, and diastolic (the bottom number) remaining at less than 80. This was previously called “prehypertension,” a category that has been eliminated. Primarily lifestyle changes are recommended.
- ◆ Stage 1 high blood pressure, with a diagnosis of hypertension is now between 130 and 139 systolic or between 80 and 89 diastolic. Lifestyle changes plus medication are recommended if patient has experienced a cardiovascular event or is at high risk of heart attack or stroke, has diabetes mellitus, chronic kidney disease or atherosclerotic risk.

- ◆ Stage 2 high blood pressure is now over 140 systolic or 90 diastolic.
- ◆ Hypertensive urgency is indicated if the top number is over 180 and/or bottom number is over 120, with patients needing prompt changes in medication if no other problems are present, or immediate hospitalization if there are signs of organ damage.

Blood Pressure Categories

BLOOD PRESSURE CATEGORY	SYSTOLIC mm Hg (upper number)		DIASTOLIC mm Hg (lower number)
NORMAL	LESS THAN 120	and	LESS THAN 80
ELEVATED	120 - 129	and	LESS THAN 80
HIGH BLOOD PRESSURE (HYPERTENSION) STAGE 1	130 - 139	or	80 - 90
HIGH BLOOD PRESSURE (HYPERTENSION) STAGE 2	140 OR HIGHER	or	90 OR HIGHER
HYPERTENSIVE URGENCY (consult your doctor immediately)	HIGHER THAN 180	and/or	HIGHER THAN 120



Generic vs. Brand Name Drugs: Rx for Savings

They account for a full 89 percent of prescriptions dispensed in the United States, but only 26 percent of total drug costs.* They're sold for a fraction of the price of their brand name counterparts. They're used to effectively treat many of our most frequently occurring ailments, including poor mental health, hypertension, ulcers and high cholesterol. Yet, despite their solid value and proven efficacy, generic drugs still suffer from an image problem in our brand-centric world. Many consumers feel that a 'no-name' drug at discount price must somehow be weaker than or work less efficiently than the brand name.

It may help to understand the economics behind drug prices. The most recent analysis by the Tufts Center for the Study of Drug Development pegs the average cost to develop and gain marketing approval for a new drug at \$2.558 billion, based on estimated average out-of-pocket costs of \$1.395 billion and time costs (expected returns that investors forego while a drug is in development). Once approved, the patent time for an average brand name drug is 12 years on the market, at which point other companies are allowed to produce a generic version.

Did You Know?

\$253 billion:

Amount saved by Americans in 2017 on generic drugs

80%:

Average savings on generic equivalent of a brand-name drug

Sources: Commonwealth Fund, *Annals of Internal Medicine* 2016

Applications for proposed generic drugs are not required to provide independent evidence of the safety and effectiveness but instead are able to rely on FDA's findings for the previously approved brand name version. Therefore the billions of dollars spent on research and development, testing and marketing has already been done, resulting in a much less costly and time-consuming launch process (and improving, see sidebar at right). The savings are passed on to pharmacies, and ultimately to patients. For patients



with chronic conditions that require medicines in the long term, the cost savings can be significant.

Quality concerns, eased

A generic drug gains approval only if it is the same as its brand name counterpart in terms of active ingredient, conditions of use, quality, purity, safety, dosage form, strength and route of administration, and must meet the same standards of quality and manufacturing. However, a generic drug may have different inactive ingredients. Two large studies performed by FDA to determine the variation in absorption between brand name and generic drugs showed a variation of 3.5 percent - a percentage so small that it can occur between two batches of the same brand-name drug.

The only caution is that switching from a brand to a generic or switching between different generic companies may cause problems for a small number of people with certain conditions. These include difficult-to-treat seizures, thyroid problems and anti-rejection medications after a transplant. Should you have questions on use of generic drugs to treat your individual condition, please ask at your next visit to our office.

Terms to know

Finally, be an informed patient when it comes to generics by understanding the following:

Authorized generics are replicas of a brand name drug, containing the exact same active and inactive ingredients as well as shape and color; the only

exception is the brand name cannot be used on the label. As of February 2018, the FDA website lists 1,122 authorized generic drugs.

Bioequivalent. All generic drugs are required to use the same active ingredient and work in the same way and in the same amount of time as the brand name drug.

Biosimilars are generic versions of biologic drugs, such as monoclonal antibodies and injectables. Due to the complex structures of biologics, it is impossible to create a precise generic version; hence the term "biosimilar." Several have already been approved for use in treatment of breast and stomach cancer, inflammatory bowel disease and rheumatoid arthritis, and more are in the pipeline.

*Quintiles, IMS

Generics have a banner 2017... with more to come in '18

Thanks to current FDA Commissioner Scott Gottlieb's laser focus on easing the process to bring generic drugs to market, many more will be available to consumers. In 2017, he pared the backlog of 2,800 pending applications down to the low 100s, shortened the review period from 31 months to a year or less, and approved a record 1,000+ generic drugs. By comparison, just 651 generics were approved in 2016 and 492 in 2015.

This year, Dr. Gottlieb plans to further enhance the availability of generic drugs and help create more choices for consumers:

- ◆ reduce strategies sometimes adopted by branded companies to delay generic drug entry e.g. restricting access to testing samples of branded drugs
- ◆ resolve scientific and regulatory obstacles that can make it difficult to win approval of generic versions of certain complex drugs e.g. medicines such as metered dose inhalers for asthma, injectable drugs
- ◆ improve the efficiency of the review process to reduce the time needed for approval



While we usually focus on what we eat to help sustain wellness, this time we look at what we don't eat and how that impacts the health of our country. It's a well-documented fact that 40 percent of food in the U.S. is wasted and is the number one contributor to our overflowing landfills. Now consider that one in eight Americans do not have a steady supply of food, and it's clear why reducing food waste has become a top priority for everyone along the food chain, from farm to fork to home. In fact, the Environmental Protection Agency (EPA) has set an ambitious goal of halving America's food waste by 2030.

Home consumers are unknowingly the largest contributors to the problem, so the opportunity to

Did You Know?

\$1,800: Money spent annually by families on food not used

400: Pounds of food wasted in the U.S. annually per person

adopt a few meaningful changes is compelling. These recommendations from the National Resource Defense Council are easy to implement, and can literally make a world of difference:

- ◆ **Shop wisely.** Plan meals, use shopping lists, buy from bulk bins and avoid impulse buys. When planning a dinner party, check out this online tool at savethefood.com/guestimator to help you calculate how much food is necessary, by factoring in variables such as how many "big eaters" are attending, leftovers desired and type of menu.
- ◆ **Buy "ugly" produce.** Many fruits and vegetables are thrown out because their size, shape or color are not perfect, but they are safe, edible and less expensive.
- ◆ **Learn when food goes bad.** Most food can be safely consumed well after their package dates (except for baby formula). "Sell-by" dates indicate how long the

store should display the product and "use-by" dates are manufacturer suggestions for peak quality. For more information, foodsafety.gov/keep/charts/storagetimes.html

- ◆ **Make the most of your food.** Move older food products to the front of the fridge/cupboard/freezer and just-purchased ones to the back, making it more likely foods will be consumed before they go bad. Keep your refrigerator at 40 degrees Fahrenheit or below to prolong the life of foods. If you have several foods that might go to waste at the same time, try adding them to adaptable recipes for salads, soups, pasta and casseroles. Freeze fresh produce and leftovers if you won't have the chance to eat them before they go bad.
- ◆ **Dine out thoughtfully.** Restaurants will often provide half-portions upon request or ask them to pack up extras to take home and eat later. Surprisingly, only about half of Americans ask for "doggie bags" at restaurants, and what's left on the plate most often winds up in the landfill.
- ◆ **Donate.** Non-perishable and unspoiled perishable food can be given to local food banks, soup kitchens and food rescue programs.

Sources: Save the Food, UNL.edu