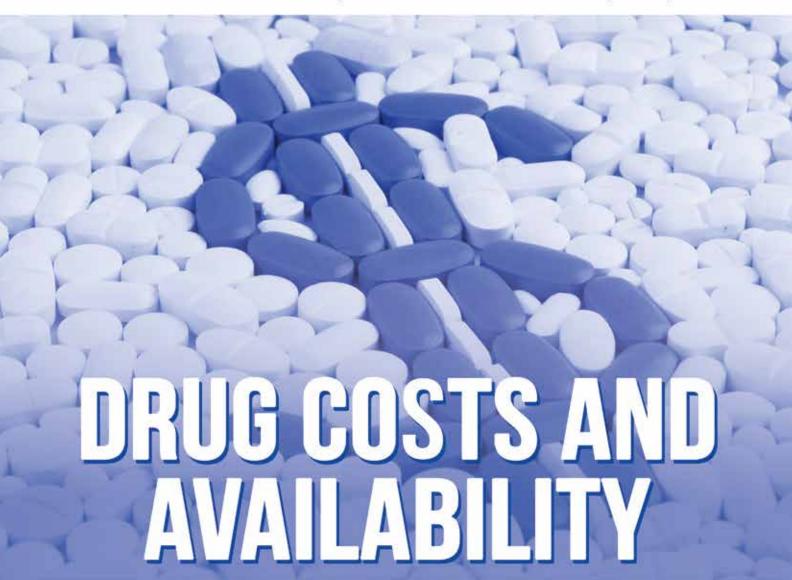
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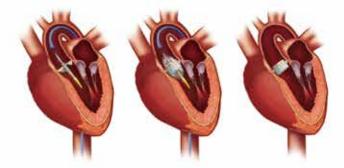
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(Telegram & Gazette reprint)

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Susan Spencer, Telegram & Gazette Staff

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# **Guest Editorial**

Michael Malloy, PharmD



Michael Malloy, PharmD

The development of generic drug companies years ago was an attempt to create a business model that provided a low-cost alternative to costly brand-name medications while being just as effective. Theoretically, these generic medications would help drive down the overall cost of drug therapy over time, which could help keep the overall cost of health care from rising too fast. Unfortunately, as time has progressed, this has not always proven to be

the case for several reasons, which are so eloquently presented by several of our authors. In fact, the cost of drug therapies continues to rise at a rate that is faster than inflation, even with the use of generics.

The authors emphasize that now, more than ever, choosing the proper medication to treat your patient has become extremely complex. It is not enough just to consider if the medication is safe, efficacious and is rooted in evidence-based medicine when making your choice. One must take into consideration such factors as insurance coverage, drug availability and the ever-increasing availability of specialty medications.

Dr. Leslie Fish, vice president of Pharmacy Services at Fallon Health, elucidates the insurer's perspective on the rising costs of drug therapy. She points out several reasons for the rising costs, such as the increased costs of generic and brand medications, the increased utilization of specialty and orphan medications, the increased costs of oncology medications and the sites of care (which dispenses the medication and where the medication is disbursed). Dr. John P. Clark, medication safety and drug policy pharmacist at

Lahey Hospital, articulates a point of view that the FDA created a policy in 2006 to create a safer environment concerning the utilization of generics. This led to the unintended consequence of removing certain generic medications from the marketplace and replacing them with more expensive branded medications. This can lead to an increase in budgets for hospitals and clinics.

Dr. Paula Evans, et al., from the Pharmacy Outreach Program at Massachusetts College of Pharmacy and Health Sciences, point out another unique factor that has contributed to the rise in generic prices: tiered pricing structures and requiring prior authorizations for generics. The tiers consist of preferred and non-preferred generics.

Dr. Joseph Sawicki Jr., lead clinical pharmacy coordinator at Saint Vincent Hospital, points out that shortages of generic medications is another factor leading to the increased cost of generics. These shortages can happen in commonly used medications (IV NS, methimazole) and are caused by a variety of reasons—manufacturing issues, raw material issues, a business decision to discontinue production, patent issues and simple supply/demand.

Dr. Melvin H. Defrin, president of Vitreo-Retinal Associates, deftly articulates how the development of therapeutic agents, anti-VEGFs, revolutionized the treatment of devastating retinal vascular disease. He points out that the choice of which agent to utilize can significantly impact the economic burden to the patient and society. The range of cost for effective drug therapy can range from \$30 to \$2,000, depending on the agent used for treatment.

I also would like to encourage you to read our feature articles that include As I See It (an essay on a career in cancer, Dr. Sidney P. Kadish), Legal Consult and Society Snippets. We have also reprinted two articles from the Worcester *Telegram & Gazette* that were presented at the 25<sup>th</sup> National Doctors Day. I hope you enjoy reading the articles as much as I did.



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# Worcester District Medical Society:

# A tradition of service and excellence in enhancing the health of Central Massachusetts residents since 1794

Frederic Baker, M.D.



Frederic Baker, M.D.

The following is an adaptation of the speech Dr. Frederic Baker delivered to more than 120 members and guests at the Worcester District Medical Society's Annual Business Meeting on Wednesday, April 8, 2015.

I want to thank you very much for allowing me the privilege of serving as your president, but most of all, I want to thank you for making the Worcester District Medical Society the success it is.

Many of us in medicine are familiar with the many acronyms that at times haunt us – ACA, ICD-10, SGR, ACO, HIPPA. Although they may represent specific principles or objectives, they can evoke different emotions and thoughts, which we may choose or choose not to embrace. But perhaps the one acronym with which we most identify and embrace is W-D-M-S, because the acronym WDMS, I would offer, is best identified as Y-O-U.

Without YOU there would be no WDMS. Without you – your dues, your generosity, your energy and without your commitment – we would be unable to provide the wonderful programs that serve our community. The WDMS is responsive to your needs, and you are the ones who help to define the agenda. Membership in a society must always have value if an organization is to stay vibrant and relevant. As we look around this room, observe and admire the talent around you. Multiple specialties, different generations, divergent backgrounds and ideologies are together as one in this room and in this medical society. Each one of you has volunteered to participate in a cause that is far greater than yourselves. All this great talent,

wisdom and experience converge and expand to make the Society as robust as it is. No other organization in Central Massachusetts can boast of a membership that encompasses the medical school, all the hospitals, medical groups, diverse practice arrangements and the multiple specialties. Any differences or distinctions serve not to divide, but to enhance and enrich our mission of a shared vision, where our collective efforts are truly synergistic and far more powerful as a force of positive impact.

The WDMS was founded in 1794. We celebrate the 221<sup>st</sup> anniversary of the Worcester District Medical Society. That's a significant milestone, as that predates the construction of the Boston Statehouse by four years. But what is most remarkable is not the longevity, but the ongoing mission and tradition of service and professional excellence, as evidenced by what we have accomplished and continue to pursue. It's hard to believe that a year has passed so quickly since our last annual meeting. I'd like to highlight some of the events we sponsored and review some of our accomplishments and how they correlate to our mission.

The district medical society consists of students, residents and physicians and continues to grow at more than 2,100 members. We also share a wonderful, longstanding collaboration with the Alliance in pioneering health initiatives.

We are the third largest district in the state and the third oldest medical society in the U.S. One of the most important responsibilities of the medical society is that of inspiring, mentoring and supporting the future generation of physicians. Thanks to your generous contributions, we were able to provide some students with scholarships for their medical education. We are so fortunate to have so many active student and resident members who remain engaged, serving as delegates, submitting resolutions and working in the community. We also sponsored a financial planning seminar that was very well received by the students.

In our mission of advancing medical knowledge, we try to present unique and practical educational programs. We had the pleasure of hosting a lively forum on the risks and benefits of medical marijuana, a very well attended event that reviewed some of the ethical, legal and medical challenges, as well as presented patient perspectives. Likewise, our annual oration by Dr. Paul Steen presented a very moving and thought-provoking presentation on the use of art and the humanities in medical training and their applications for enhancing observation skills, which are so critical for excellent medical care.

Enhancing the health and welfare of individuals and communities is one of the cornerstones of the Worcester District Medical Society. We take pride in the collaboration with the Department of Public Health to provide its annual Community Immunity Flu Vaccine Clinic for all Worcester residents; the barbershop men's clinic; the gun buyback program; and the Worcester District Medical Society Rx Fund. This fund provides transitional assistance with prescription medicine to patients of WDMS members while they await approval for insurance coverage.

Health Matters is our biweekly community health affairs TV program, which has done 140 TV shows in a half-hour interview format. It offers valuable information on disease prevention and treatment options. We have the distinction of being the only district to sponsor a television show and magazine. We also take pride and honor our colleagues who inspire us in their service to their patients and communities, such as tonight's award recipient for Community Service, Dr. Mattie Castiel.

Another commitment of the WDMS is that of advocacy. Although we are truly privileged to fulfill a unique calling in this great profession, the ever-increasing demands and expectations can at times prove equally exhausting and overwhelming. The WDMS is here to serve as your ally, resource and advocate.

Just recently, we had the privilege of hosting a legislative breakfast. That brought together 27 physicians with 14 individuals representing senators, representatives and aides in a positive exchange of ideas and issues that pertain to clinical practice and patient care. The WDMS is committed to educating and collaborating with lawmakers to adopt policies that seek to foster a practice environment that is sensible, affordable, sustainable and satisfying for all stakeholders. Ideally, we seek policies with minimal disruption of patient access and workflow, where all stakeholders share burdens and responsibilities in such a way that there is no disproportionate burden, cost-shifting or unforeseen adverse consequences from what may initially seem benevolent. Transparency and truly meaningful use must be evident for all and not just a label.

Many of you may be familiar with the recent editorials and articles in the Worcester *Telegram and Gazette* addressing gun safety and preserving the patient-physician relationship and free speech. For those of you not familiar, lawmakers in the state of Florida adopted laws prohibiting physicians from asking about gun ownership and gun safety. Thanks to the courageous, thoughtful and diligent efforts of Drs. Mike Hirsh, Leonard Morse and Jay

Broadhurst and students Patrick Lowe and Patrick Alvarado, the WDMS presented a resolution that was unanimously accepted by the MMS. In honor of the 25th anniversary of Doctor's Day, the WDMS and MMS raised public awareness about preserving free speech and confidentiality in the patient-doctor relationship. Many of us have the privilege of serving diverse populations that include members of the military, law enforcers, businesses owners, hunters and responsible gun enthusiasts. Gun safety is just as relevant to patient-physician discussions as are discussions on nutrition, addiction, sexual activity, occupational hazards and sport risks. As inconvenient as it may be for some to accept the reality that the pursuits of personal freedoms may sometimes lead to substantial harms, there is no denying the fact that such discussions can lead to better outcomes.

Today, it may be the government restricting physician free speech; tomorrow, it could be an insurer, an employer or anyone who perceives or distorts free speech as threatening or uncomfortable. No one is safe if that happens. Now, more than ever, the unity, clarity and positive voice of organized medicine, as embodied by the WDMS, is one that must always register and be heard. Organized medicine must never be silent on issues that impact individual and public health. The public deserves the unbiased, experienced, rational and compassionate voice of the medical society. Whether it is an Ebola, flu or opioid epidemic; medical marijuana; vaccine safety; palliative care; the benefits and safety of fluoridation; or caring for the underserved, we must never surrender or acquiesce to those who are less informed or to those who choose carelessly to distort, deny or withhold facts, exploit irrational fears or suppress free speech in order to pursue a hidden agenda. Thanks to a great editorial board and the collective efforts of authors from the medical and lay communities, our bimonthly magazine, Worcester Medicine, has served as a forum for such dialogues and the positive exchange of ideas on such issues. The magazine continues to address critical issues and other important healthcare issues facing Central Massachusetts.

I want to thank all of you for your confidence and support. Thank you very much to my colleagues in my call group for covering me to allow me to fulfill my duties as president. Thank you to my wonderful wife, Kathy, and my family, who are always there for me. A special thanks goes to Joyce Cariglia. For those not familiar with Joyce, she is our executive director, and for 30 years, she has continued to serve the WDMS in a capacity that makes all of this possible. She serves to inspire current and past presidents with her warmth, energy and knowledge.

In closing, the positive impact of organized medicine in the lives of others — whether advocacy, expansion of knowledge, community service, networking or mentoring — is evident each and every day in the work of the WDMS, and it's thanks to all of you that this is possible. Please, stay engaged and continue to share your talents, thoughts and support, as you are what make the Worcester District Medical Society the success that it is and deserves to be.

Thank you.

# Generics: Not always affordable

Paula Evans, PharmD, MS, CGP; Colleen Massey, MS; and Karrie Juengel, PharmD



Paula Evans, PharmD, MS, CGP; Colleen Massey, MS; and Karrie Juengel, PharmD

Over the past few years, some older generics have had huge cost increases, and in recent months, an even greater number of them have accelerated in cost. Common older medications that experienced a recent increase include doxycycline, captopril, clomipramine, digoxin and levothyroxine. Often, prices of newer generics, such as valsartan, do not drop immediately after patent expiration, as some generics are given a period of exclusivity to the market for about six months. At the end of that time period, several generic manufacturers may produce the drug, and the price will tend to decrease.

Generics account for approximately 80 percent of all prescriptions filled in the United States, and therefore, an increase in cost of these medications is of concern. According to Catamaran, a pharmacy benefit manager that administers prescription drug programs, consumers and insurers paid an average of \$13 per prescription for the 50 most popular generics in 2010, and in 2014, they paid an average of \$62. In addition, in 2014, 33 percent of all available generic medications cost the consumers and insurers more than \$100 per prescription. As health care providers, it may be wrong to assume all generics are affordable. Major factors for generic cost

increases are numerous and include industry consolidation, drug shortages, increased regulatory measures and supply disruptions.

As indicated previously, when a branded drug loses patent, multiple generic manufacturers produce the drug, resulting in price competition and, in time, significantly lower costs. Prices of generics are lower than brands - about 80-85 percent of the brandname cost, as generic companies are not required to repeat clinical trials (since Hatch-Waxman Act, 1984). As the years go by with lower profit margins, fewer manufacturers produce a particular drug (sometimes only two or three companies), and generic prices trend upward. With fewer companies, if there is a regulatory issue or a problem with obtaining raw materials, drug shortages can be common and, with increased demand, lead to price increases.

According to the FDA, quality and manufacturing issues are the major reasons for drug shortages, as the FDA monitors every facility that is used for production. The manufacturing processes used by some of the companies importing generic medications into the United States have been investigated more stringently by the FDA. Some foreign manufacturing facilities have been banned from producing or distributing any drugs, and this has caused delays in products that then have to be produced locally. In other situations, should a manufacturing problem arise within a company and need correction, the FDA has even required a rigid approval process to transfer production to another facility within the company. The impact of the increased FDA quality controls has contributed to some companies closing rather than spending more on quality measures.

More and more, health insurers are starting to pass along the increasing cost for generics to the patient by implementing tiered pricing structures and requiring prior authorizations. Generic medications are now being placed in preferred and non-preferred tiers. Generics in non-preferred tiers have higher co-pays and can be problematic if the medication is a first-line product. Over the past year, it is noted that an increasing number of insurers are using a five-tier formulary. The first two tiers are preferred and non-preferred generics; the third and fourth tiers are preferred and non-preferred brands; and the fifth tier is for specialty medications. Insurers are also requiring prior authorizations for some generics, creating an additional barrier for the patient and slowing the process of treatment. Major branded drugs that lost patent protection in 2014 and are already available/soon to be available as generics are Abilify (aripiprazole), Nexium (esomeprazole), Cymbalta (duloxetine), Copaxone (glatiramer), Lantus (insulin glargine), Diovan (valsartan)

and Celebrex (celecoxib). These agents could likely be included as tiered generics and/or require prior authorizations.

There are assistance programs available to help out with some generics at both retail and mail-order pharmacies. The generic discount drug program, offered by Walmart, Target and others, offers some generic medications for \$4 for 30-day supplies and \$10 for 90-day supplies. These programs can help patients to access their medications, and a recent study showed they have increased in use (26 percent) by all patients - no matter age, educational level, income or racial/ethnic group. 1 They do not require insurance claims to be filed, and program users often have insurance coverage.

Generic prices are in a state of flux, and patients should be aware and seek assistance if prices suddenly seem out of line. As health care providers, we need to be connected with our patients' needs and not assume all generics are affordable.

All Massachusetts patients and providers are welcome to contact the MCPHS University Pharmacy Outreach Program at 866-633-1617 for medication related concerns, including affordability of medications.

Consumers call the Pharmacy Outreach Program on a daily basis about the cost of their medications, and within the past year, more and more individuals have been struggling with the cost of their generic drugs, despite their increase in availability. Recently, a Medicare beneficiary phoned with concerns regarding the cost of her generic lidocaine patch, which was newly prescribed by her health care provider. While trying to fill the prescription at the retail pharmacy, she learned the medication would cost approximately \$270 for a 30-day supply.

Upon further research, staff at Pharmacy Outreach learned that the generic lidocaine patch was more expensive on the client's Medicare Part D prescription drug plan than the brand Lidoderm because the generic lidocaine was non-formulary and the patient would be forced to pay the full price of the medication. Another plan was sought, and the best available for coverage offered the generic and brand at the same formulary tier level – Tier 3: Preferred Brand - with a \$35 copayment. The patient was able to switch plans. At the current time, even though the generic lidocaine is available on the market and most would assume the price would be lower – even the prescriber – not all prescription plans offer coverage of the specific generic medication. Additionally, when the generic agent is available, the price is often similar to the brand, as noted by the tier the agent is placed on the formulary.

Paula Evans, PharmD, MS, CGP, is an assistant professor of pharmacy practice and director of the Pharmacy Outreach Program at MCPHS University. Colleen Massey, MS, is director of operations of the Pharmacy Outreach Program at MCPHS University. Karrie Juengel, PharmD, is the current geriatric fellow of the Pharmacy Outreach Program at MCPHS University.

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# Safer medications: At what cost?

John P. Clark, PharmD, MBA, BCPS



John P. Clark, PharmD, MBA, BCPS

The federal government has long regulated medications and medical devices. Dating back almost 100 years, the original Federal Food and Drugs Act of 1906 was the first federal law to regulate drugs. This act addressed adulterated or misbranded products and required that drugs meet certain standards for strength and purity, but not safety. It wasn't until 1938, when the Federal Food Drug and Cosmetic Act (FFDCA) was passed, that medications were evaluated for safety also. Finally, the act was amended in 1962 to include efficacy. This revolutionized the drug marketing process, as manufacturers were required to demonstrate that

their products were both safe and efficacious to the U.S. Food and Drug Administration (FDA). Along with this amendment, the Drug Efficacy Study Implementation (DESI) review occurred for all drugs marketed between 1938 and 1962. The DESI review allowed for a retroactive evaluation of safety and efficacy of all newly marketed drugs within this time period. Despite this, there continues to be medications that have not received appropriate FDA approval available in the U.S. market.

Unfortunately, many patients and health care providers are unaware that these medications have not received proper FDA review and approval. Often, the label of these drugs does not disclose the absence of FDA approval. There is also an assumption that these drugs are generic medications because they have been marketed without a brand name and have been marketed for such a long period of time – some predate the FFDCA. This is not actually the case, as generic medications are subject to an FDA approval process as well. The process for a generic medication is slightly different, as the manufacturer is subject to demonstrating bioequivalence to the brand-name reference drug. These generic medications have met all of the same quality, strength and purity standards of the original brand-name medications. Unapproved medications may not have the same quality or safety as those formally reviewed by the FDA.

Back in June 2006, the FDA rolled out a drug safety initiative to remove these unapproved drugs from the U.S. market. At this time, the FDA released guidance outlining its enforcement policies to effectively bring all medications into compliance (either by removal from the market or appropriate approval). The FDA was to focus resources on those medications that posed the most serious risk, while at the same time, attempting to minimize impact on the market; in essence, avoiding significant drug shortages. The risk-based enforcement program gave highest priority to:

- Drugs with potential safety risks.
- Drugs that lack evidence of effectiveness.
- Health fraud drugs.
- Drugs that present direct challenges to the new drug approval and OTC drug monograph systems.
- Unapproved new drugs that are also violative of the Act in other ways.
- Drugs that are reformulated to evade an FDA enforcement action.

The health care marketplace is really starting to experience the impact of this initiative. The FDA has already moved against some medications, such as quinine and colchicine. Both of these medications were previously available as unbranded products, yet neither had obtained appropriate FDA approval. Since the FDA action, both of these oral medications have had branded products reviewed and approved. This is not without risk, however. Colchicine, for example, was approved by the FDA with different dosing compared to the historical dosing used by providers. This is directly related to how the new product was studied in the clinical trials that provided evidence of safety and efficaciousness. There is an impact to patients, as well. These branded products carry higher acquisition costs, as well as higher co-pays for a medication for which a patient may have paid a lower co-pay (i.e., generic co-pay rate) previously. There are also some medications that have become single manufacturer and have correlated increases in cost. In the acute care setting, two more recent medications that have impacted service are neostigmine and vasopressin.

Neostigmine is now marketed under the brand name Bloxiverz and is indicated for post-operative reversal of effects produced by non-depolarizing neuromuscular blocking agents (NMBAs) administered during surgical procedures. Originally introduced in 1931, it predated the FFDCA, and multiple products were marketed under a grandfather provision until recently. Despite the FDAs attempt to mitigate drug shortages in this process, this medication did have supply issues for a period of time. The cost of this newly approved product is tenfold more expensive than the previous versions that did not carry FDA approval.

Another medication making a large impact is vasopressin. Vasopressin is now marketed as Vasostrict and is indicated to increase blood pressure in adults with vasodilatory shock (e.g., post-cardiotomy or sepsis) who remain hypotensive despite fluids and catecholamines. The medication has more than just a financial impact, although there is a staggering twentyfold increase in cost. The other factor facing health care facilities is the new storage requirement. Vasostrict needs to be stored under refrigeration. Previously, this medication was often stored in Code Blue Resuscitation ("crash") carts or in operating rooms to allow clinicians quick access to this emergent medication. The refrigeration factor is causing facilities to evaluate how to ensure timely access to this medication.

The aforementioned neostigmine and vasopressin have the ability to have a six-figure impact on the budget of an average hospital. Overall, the FDA approval process ensures that there are safe and effective medications available for patients, yet it is not without concern. As witnessed by the examples above, there has been impact to supply, as well as overall costs.

John P Clark, PharmD, MBA, BCPS, is a medication safety and drug policy pharmacist at Lahey Hospital and Medical Center. He is also adjunct professor of pharmacology at Regis College.

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# Cause, effect and cost: A short history of drug shortages

Joseph J. Sawicki Jr., PharmD, RPh



Joseph J. Sawicki Jr., PharmD, RPh

Drug shortages have increased during this decade. The University of Utah Drug Information Service has tracked the number of medication shortages quarterly from 2010, and the data has shown an upward trend. On the last day of Quarter 1 in 2010, there were 152 drug shortages reported, compared with the last day of Quarter 4 in 2014, where 301 drug shortages were reported. These shortages are represented across many classes of medications, including, but not limited to, CNS agents, antibiotics, IV fluids, electrolytes and several other categories.

The reasons for drug shortages are very complex and multifaceted. Some broad-brush causes

include manufacturing issues, raw material issues, business decisions to discontinue drugs, patent issues and supply/demand issues. Many times, the root cause is a combination of one or more of the aforementioned causes, and many times, there is no explanation that can be found.

I will focus on some examples of the shortage issue that I find very fascinating, both from an ethical and clinical perspective. When multiple manufacturers have medications on the market, there is competition, so the prices of the products remain fairly constant and there is a built-in protection for a potential shortage.

Back in 1998, Puerto Rico was hit by hurricane Georges. The only manufacturing facility in the U.S. that made brand-name oral methimazole and other medications was damaged, and all production of these medications ceased. This caused a significant shortage, as there was no other facility that could produce the medications. Methimazole is a "must have" medication. How could this happen? Patients missed doses or self-medicated partial doses to make their medication last as long as possible. This brought up the question of why there was a lack of redundancy, meaning should there be multiple manufacturing plants in different locations that could better supply the market in case of a disruption?

Let us look at the current issue surrounding the availability of IV NS (0.9% Sodium Chloride), which is used by many hospitalized patients on a daily basis. There are three companies that manufacture IV NS in the United States: Hospital, Baxter and Braun. Starting late in 2013, there were delays in production from some of the manufacturers; however, it was felt that this should have no impact on satisfying market demands. Starting early in 2014, there was an unprecedented spike in demand of IV NS, and even with all three companies producing product at full capacity, they were unable to keep up with demand and this resulted in widespread shortages. Now add any recalls to this mix, and the shortages become

even worse. The FDA has allowed these three companies to import IV NS from their plants in Europe to help satisfy the increased demand in the U.S.

Another shortage worth mentioning is IV phentolamine. This is used both as an antidote for peripherally administered vasopressors that extravasate and for treating pheochromocytoma. There was both a generic and a brand-name product on the market until 2000, when the brand name was discontinued. The generic product continued on the market until early January of 2015, when the company decided to cease manufacturing. As of April 2015, there is no product available on the U.S. market, so alternative treatment modalities should be used.

The U.S. drug market can be very complex; case and point is a list of medications that are designated as DESI drugs. DESI stands for Drug Efficacy Study Implementation and was part of the Kefauver-Harris Drug Control Act. This meant that any medication introduced to the market between 1938 and 1962 had to be classified as either effective, ineffective or needs further study. There are several medications still being used today that are DESI drugs that were deemed effective (and safe). These medications did not need FDA approval and were able to remain on the market in the U.S. Colchicine is one of these products, and it has an interesting story behind it.

Colchicine tablets had been on the market as a DESI drug (with no FDA approval) until 2009, when a company obtained FDA approval. In late 2010, the FDA ordered all companies that did not obtain the FDA approval to cease production immediately. The price for colchicine went up dramatically, from \$0.09 per tablet (non-FDA-approved product) to \$4.85 per tablet (FDA-approved product).

Vasopressin was discovered in 1895 but had never been FDA approved until April of 2014, when a company named Par received approval and introduced Vasostrict. There were generic versions being manufactured by two other manufacturers; although they were not FDA approved, they were still widely used and the cost was minimal. These products were stored at room temperature and carried an extended expiration date (12-18 months). Once the FDA approved the new vasopressin, the companies that were providing the non-approved formulation were removed from the market and cannot be manufactured anymore. This left Vasostrict as the sole product on the market. The cost also went from about \$5 per 20-unit vial (for the generic, room temperature formulation) to almost \$60 per 20unit vial (the FDA-approved formulation). The new-to-market formulation of vasopressin has different storage requirements. The product is stored in the refrigerator, and if the product is stored at room temperature, the expiration date changes to 90 days (which can be confirmed by calling the company directly).

In closing, these are a small sample of drug shortages. I ask anyone who made it through the entire article to please be patient when you receive the news a medication is not available. Shooting the messenger is bad karma.

Joseph J Sawicki Jr., PharmD, RPh, is the lead clinical pharmacy coordinator at Saint Vincent Hospital.

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# The rise in drug costs: An insurer's perspective

Leslie S. Fish, PharmD



Leslie S. Fish, PharmD

The goal of health insurers like Fallon Health is to keep plan premiums down while affording the best possible care for members. Fallon works to spend 90 percent of every premium dollar on medical care and only 10 percent on administrative costs. However, ongoing medication price hikes greatly contribute to the cost of health care and directly impact health insurance premium costs.

Currently, prescription medications account for 10 percent of all health care costs 1 in the United States and are rising at rates far above

inflationary trends. In this article, we will explore the aggressive pricing trends among both new and existing generic, branded and specialty medications and how insurers respond to these price increases.

#### **Generic medications**

Generic medications are responsible for 85 percent of utilization in the U.S. but represent only 30 percent of all pharmacy costs.2 Although they are less expensive than alternative branded products, their costs have increased at a rate of 10 percent over the last 18 months. Certain medications have had remarkable price increases.

Generic medication	Cost 2013	Cost 2014
Tetracycle 250mg	\$0.05/tablet	\$4.26/tablet
Tetracycline 500mg	\$0.06/tablet	\$8.59/tablet
Albuterol sulfate 2mg	\$11.00/#100	\$434.00/#100
Doxycycline 100mg	\$1.12/#28	\$103.54/#28

Based on Average Wholesale Price (AWP).

What's causing these price hikes? There are several factors: Some generic manufacturers have stopped making certain products, thereby decreasing competition; new generic manufacturers have been blocked from getting into a medication "space" by already established manufacturers; there are raw material shortages and shortages of ingredients due to manufacturing problems; generic manufacturers have merged; and there is a backlog for new generics at the Food & Drug Administration (FDA).

#### **Branded medications**

Branded medications also are contributing to the rising costs. For example, in 2013, utilization in hypoglycemic agents for diabetes treatment increased by 2.4 percent, and costs increased by 11.6 percent, for a total increase in spending of 14 percent.3 Some of this increase was due to the introduction of new, expensive agents, such as the DPP4s, GLPs and SGLT2 agents, while some of it was due to cost increases in products such as the insulin Lantus. Although the newer anti-diabetic agents are very costly, their clinical value is no different than the less expensive generic alternatives.

Medication	Date of Increase	Increase (%)	
Lantus	4/26/2013	9.9	
	8/02/2013	14.9	
	12/13/2013	14.9	
	05/30/2014	16.1	
	11/07/2014	11.9	

Based on Average Wholesale Price (AWP).

#### **Specialty medications**

Specialty medication trends are rising the most at 21 percent to 25 percent per year. Spending on all prescription drugs totaled \$319 billion in 2014, 1 with specialty medications accounting for 25 percent of it. It's estimated that specialty medications will account for more than half of all costs by 2019.4 By 2020, this amount is expected to quadruple from \$87.1 billion to \$401.7 billion.5

Specialty medications are used in a variety of diseases, and the list is growing weekly. Some of the diseases they treat include rheumatoid arthritis, multiple sclerosis, psoriatic arthritis, Crohn's Disease, Cystic Fibrosis, HIV and cancer. Examples of these medications include Enbrel, Humira, Copaxone, Betaseron, Gonal F and Nupogen. The rise in cost is due to new medications being marketed, as well as increases in existing products. These products now average \$4,000 to \$6,000 per patient per month. Specialty drug price increases:

Medication	Date	Increase (%)
Avonex	03/02/2012	8.5
	08/31/2012	5.8
	11/30/2012	4.5
	06/28/2013	7.5
	11/16/2013	8.0
	09/13/2014	5.0
Copaxone	01/03/2012	14.9
	10/01/2012	4.9
	01/01/2013	9.9
	01/01/2014	9.9
	08/22/2014	9.9
	01/01/2015	9.9

Based on Average Wholesale Price (AWP).

#### **Orphan medications**

The FDA defines "orphan diseases" as those that affect 200,000 or fewer people in the U.S. The FDA can deem medications to have "orphan indications." Products that receive an orphan status command very high "orphan" prices whether they are used for an orphan disease or another, more common disease. Unfortunately, once a medication cost is set for the orphan condition, that same rate is paid for the drug to treat the non-orphan condition. Below is a table with medications that have orphan indications for one disease, but are used more commonly in other diseases.

Medication	Orphan utilization	Non-orphan utilization
Remicade	53%	47%
Rituxan	58%	42%
Avastin	31%	69%
Alimta	4%	96%
Gammagard	0%	100%
Xgeva	0%	100%
Procrit	0%	100%
Orencia	0%	100%

Data derived from Medi-Span Master Drug Database.

#### **Oncology medications**

In 2014, the overall rate of increase in average cost per claim was 22.7 percent.6 The average cost per prescription has increased from \$5,000 per month to \$12,000 per month over the last seven years. Price increases do not correlate with overall survival benefits.

Not only are new oncology products, both oral and injectable, priced higher, but the already established oncology products also have taken huge price increases. For example, Thalomid, a medication that was marketed in the 1950s as antiemetic, was reintroduced in the U.S. as a drug for cancer. The medication now costs \$356/150mg tablet. Likewise, Gleevec, another medication for cancer, has seen the cost rise by 38.2 percent over two years. In 2001, Gleevec cost \$4,540 per month; today it costs \$8,488 per month. Out of the last 12 oncology medications approved in the U.S., 11 are priced at \$12,000 to \$15,000 per month – or \$100,000 to \$200,000 per year.

Medication	Disease	Price per year or treatment
Adcentris	Hodgkins lymphoma	\$135,000
Yervoy	Melanoma	\$120,000
Folotyn	T-cell lymphoma	\$120,000

Data from Medi-Span Master Drug Database.

#### Site of care contributes to increases

Drug spending is also increasing for reasons other than market price increases. An example of this can be seen in oncology. Many oncologists are selling their practices to hospital systems. Hospital outpatient departments charge extraordinarily high rates for infused medications. A recent example shared by Medscape Medical News7 talked about a patient whose physician's office was bought by a hospital system. When she went for her Herceptin in March 2013, the cost was \$6,000, but when she went back to the same physician's office for the same drug the very next month, the cost was \$18,000.

#### **Insurers' response to medication costs**

Some of the tools that health plans are using to keep the costs of prescription medications from trending higher while ensuring that members have access to appropriate medications include:

- Contracting for medications, which means picking a preferred medication(s) in a class.
- Directing the site of care of medication administration to be in home settings instead of hospital outpatient settings when appropriate.
- Using closed formularies.
- Creating guidelines for certain diseases based upon evidencebased medicine and outcomes.

We also partner with industry associations, such as America's Health Insurance Plans (AHIP) and Alliance of Community Health Plans (ACHP), to write white papers and use lobbying efforts to bring the issue of high costs to the attention of the federal government. How prescribers can help

We encourage prescribers to be aware of medication costs and, if the data is available, compare less expensive treatments with more expensive treatments in terms of outcomes. The goal of therapy should be stated at the beginning of treatment, and progress toward that goal assessed throughout the course of the therapy. If the goal is not being achieved, re-evaluate the treatment and consider termination. One example of goal vs. outcome might be with medications to treat Alzheimer's disease. The expected outcomes of these medications are usually moderate at best and, for many people, wear off within a 12-month period. Often, people are left on these medications not because they are effective but because there are no treatment alternatives.

Working together, providers and health plans can ensure that medications are prescribed appropriately to patients and that their therapies are carefully monitored. We all have a stake in better controlling medication costs in the years ahead.

Leslie S. Fish, PharmD, is vice president of Pharmacy Services at Fallon Health. In this role, she oversees the pharmacy benefit design and the medical management of prescription medications across all Fallon products. Her focus includes integrating evidence-based treatments into care management, drug trend analysis and pharmaceutical pricing.

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### drug costs & availability

## Current therapy: Anti-VEGF agents in retinal disease

Melvyn H. Defrin, M.D.



Melvyn H. Defrin, M.D.

The last decade has seen a revolution in our ability to treat devastating retinal vascular disease, including exudative age-aedema and retinal vascular occlusions. What brought this about was the introduction of anti-VEGF agents to both arrest retinal and sub-retinal neovascularization and reduce capillary permeability.

Vascular endothelial growth factor (VEGF) is a signal protein<sup>1</sup> that stimulates angiogenesis, normally in embryonic development, after injury and in producing collateral vessels following vascular occlusion. It appears to be excessively produced in some

ocular conditions: "wet," or neovascular, macular degeneration; diabetic retinopathy; and retinal vascular occlusions (both branch and central retinal vein occlusions). There are three currently available anti-VEGF agents that function to block the VEGF protein in these circumstances when administered as an intravitreal injection: bevacizumab (Avastin) used off-label, ranibizumab (Lucentis) and aflibercept (Eylea), both FDA approved for all the above conditions.

In clinical trials and real world practice, all three agents are effective treatment. For the first time, the measure of success was not how little vision was lost with treatment vs. sham, but rather how much vision was gained and maintained in a significant portion of the recipient group. The efficacy of treatment is largely a function of whether the disease state produces excessive quantities of VEGF. In wet macular degeneration, the VEGF production is not nearly as great as in acute retinal vein occlusions and many patients with diabetic retinopathy. As a result, less inhibition is required in macular degeneration.

The choice of which agent to use is a function of multiple factors: cost, insurer approval, off-label use vs. FDA approval and duration of action. The first effective agent was Avastin. When the FDA approved Lucentis in 2006, a debate arose as to whether an inexpensive drug (Avastin) was as effective as the significantly more expensive Lucentis. The Comparison of Age-related macular degeneration Treatment Trials (CATT) in 2012² showed Avastin and Lucentis to be equivalent at two years when using similar dosing regimens, though there was some indication that monthly dosing produced slightly better visual results compared to PRN dosing. In all groups, however, 60 percent of patients achieved 20/40 or better vision at two years. A third option appeared in 2011, when the FDA approved Eylea for the treatment of wet macular degeneration. The VIEW trial³ demonstrated Eylea, dosed every two months, to be as effective as Lucentis with monthly dosing.

At this point in time, the major issue is not what is first-line treatment for wet macular degeneration, diabetic retinopathy and retinal vein occlusions. Clearly, the use of intravitreal anti-VEGF agents is the standard of care. The major issues are then: which agent, dosing regimen, treatment burden to patients and societal cost. A recent survey by the American Society

of Retina Specialists (ASRS) of member preferences showed most retina specialists beginning treatment with Avastin and very few adhering to a monthly dosing schedule. Most use "treat and extend," where the injections are administered monthly until the macula dries out, and then the interval is extended two weeks at a time (with an injection at each visit) until activity recurs, at which time the interval is reduced. Failure to respond usually stimulates a change of agent, most often today to Eylea.

The economic burden to patients and society in general is not insignificant. Nowhere else in medicine can a \$30 drug (Avastin) compete successfully with those costing \$1,800 (Eylea) or \$2,000 (Lucentis). Insurers can take advantage of this by mandating a "step" approach beginning with Avastin or removing physicians who use Lucentis and Eylea from HMO and Medicare Advantage panels. Far and away, the one disease that affects the largest cross-section of our country is diabetes. One-third of diabetics older than 40 have retinopathy. It is the leading cause of new onset blindness between the ages of 20 and 74.4 The number of people with diabetic retinopathy in the U.S. is expected to reach 16 million by 2050. Anti-VEGF therapy for diabetic macular edema has now supplanted the previous gold standard of focal laser as the treatment of choice. Clinical trials have demonstrated its effectiveness, especially when begun early. The one-year results of the Diabetic Retinopathy Clinical Research Network (DRCR) Protocol T trial<sup>5</sup> showed equal effectiveness of improving vision by all three agents when used in patients with beginning good visual acuity, but when vision was 20/50 or worse, Eylea was clearly more effective.

From both a patient and physician point of view, one of the more paramount issues is treatment burden. The need for the patient to be seen at frequent (often monthly) intervals can truly be a burden on the patient, who will need to ask friends and family for rides to the office, and the physician, who must now see these patients much more frequently with an already busy schedule. This definitely creates an impetus to develop a longer-lasting treatment.

Good quality health care is one driven by patient involvement with physician guidance. It is difficult enough deciding on treatment options without adding the additional complexity of economics. Very few patients make treatment decisions based on cost, as they are not directly involved in paying for them. It is our responsibility to provide them with the appropriate guidance.

Melvyn H. Defrin, M.D., is the president of Vitreo-Retinal Associates, P.C., and an affiliate in the Department of Ophthalmology at UMass School of Medicine.

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## A career in cancer

Sidney P. Kadish, M.D.

It is now 10 months since I retired as a full-time radiation oncologist. I had served at various institutions for a total of 41 years. Now, I feel the need to kick back and reflect.

People often asked me, "How can you do this work? Isn't it depressing?" But, for me, the answer to these questions has always been, "No! It is not depressing at all, and really, it has been curiously gratifying."

How so? The first portion of this response has to do with being constantly surrounded by wonderful examples of caring. I refer, first of all, to caring by medical professionals, of course. My doctor colleagues, as well as nurses, therapists (technologists) and all the allied health people, like social workers and nutritionists, etc., are trained to care and are devoted to the patient from the beginning of their training. Simply watching the process of the delivery of oncology care is positively uplifting in this cynical world in which we live.

But more than the practice of health care professionals, what touched me daily was the presence and actions of those unsung heroes, the caregivers. Laypeople all, the wife or husband, the son or daughter, the neighbor, church volunteer or even the divorced spouse demonstrated an unquestioning devotion, a dedication to the ill party. Whether the news was good or bad, whether the progress was up or down, I witnessed an inspiring display of caring on a daily

basis. This devotion proceeded regardless of wealth, education or social class. It was just plain person-to-person caring, a value that is in short supply in many areas of our society.

Yet the patient himself/herself is not a passive vessel that is simply acted upon by the medical system and the family. I saw that in many – if not most – instances, the cancer diagnosis aroused in the patient a desire to put up the Good Fight. Everyone knows that they are going to die, but most patients struggle and rage internally to fight to extend life. This is true, whether the patient has a curable disease or an incurable disease. Every patient wants to be around for his/her grandson's graduation or granddaughter's wedding. It seems that the knowledge of malignancy itself releases energies of will and desire that are powerful and inspiring forces.

The cancer patient comes to appreciate the simplest things in life. The patient who can walk around the block or rake the leaves in the yard is grateful for the progress he/she has made, and patients teach us, the professionals, how we must never take simple acts of daily living for granted.

In short, I have learned so much from my patients and have been inspired by them in many ways. I am blessed to have had the opportunity to work in the field these many years.

Sidney P. Kadish, M.D., is a retired radiation oncologist.

## Conditions, preconditions and the False Claims Act

Peter J. Martin, Esq.



Peter J. Martin, Esq.

Health care providers are familiar with the notion that certain things have to be true for any claim for payment for services rendered to be honored: For example, the service must in fact be provided; it must be provided by an appropriately licensed provider; it must be medically necessary; and it must be a benefit covered by the payer. Under the federal (and in Massachusetts, the state) False Claims Act, a claim for payment can be denied and the claimant held liable if the claim involves a false or fraudulent statement that is material to the government's decision to pay a claim. Under

this FCA standard, what facts are material to that decision to pay a claim, such that falsehood may lead not only to denial of the claim but liability for the provider?

A recent federal court decision involving a mental health clinic's failure to have adequately licensed and supervised therapists focuses on this question and answers it in a way that should alert providers to the notion that every claim for payment implicitly certifies the provider is compliant with a wide range of regulatory requirements. These requirements need not be explicitly linked to eligibility for payment. The decision stands for the proposition that what has to be true about a claim, and about a provider submitting that claim, can be a "precondition to payment" that is not expressly designated as such, that depends on the context, and that is deemed "material" by the governmental payer.

The case involved some undeniably horrid facts: A teenaged MassHealth beneficiary saw a series of staff members at a mental health clinic in Lawrence licensed by the Department of Public Health. Many of these therapists and counselors were either unlicensed, unsupervised or both. At one point, a nurse, held out by the center as a psychiatrist, prescribed a medication for bipolar disorder. The patient suffered an adverse reaction, and the nurse repeatedly failed to return phone calls regarding the patient's condition. After a seizure and a hospitalization, the patient resumed treatment at the center, but shortly thereafter, suffered a second, fatal seizure.

Throughout their child's treatment, her mother and stepfather raised concerns about the qualifications and supervision of the various clinicians involved in the case. After her death, they filed complaints with a variety of state agencies. The DPH issued a report concluding that in treating the young woman, the center had violated 14 separate regulations concerning staff supervision and licensure. More generally, the DPH found that 23 therapists at the center required clinical supervision, but there were no records documenting any such

supervision for a number of years.

The mother and stepfather filed a complaint in federal court under both the state and federal False Claims Acts. They alleged the center engaged in fraudulent misrepresentations and fraudulent billing based on failure to meet staff licensure and supervision regulatory requirements. At trial, the district court dismissed the claims based on a distinction between conditions of participation in the MassHealth program as a mental health center and conditions of provider payment by the MassHealth program. In the trial court's view, only violations of conditions of payment, not conditions of participation, could lead to a false claim.

On appeal, the First Circuit court rejected the relevance of that distinction. Instead, the court ruled that "[w]e ask simply whether the defendant, in submitting a claim for reimbursement, knowingly misrepresented compliance with a material precondition of payment [citation omitted]. Preconditions of payment, which may be found in sources such as statutes, regulations, and contracts, need not be 'expressly designated' [citation omitted]. Rather, the question whether a given requirement constitutes a precondition to payment is a 'fact-intensive and context-specific inquiry,' [citation omitted]." It concluded, after a review of both MassHealth and DPH regulations, that the staff supervision and licensure provisions violated by the center in this case were conditions of payment.

Many of the regulations requiring adequate supervision of staff purportedly violated by the center did not explicitly state that a provider's compliance with them was required for reimbursement. The appeals court nevertheless held that proper supervision is a condition of payment. Likewise, the provider never explicitly stated in its claims that it was in compliance with those regulations. However, the appeals court noted that the center "implicitly communicated that it had conformed to the relevant program requirements" (i.e., the DPH clinic licensure and the MassHealth mental health center regulations) each time it submitted a claim.

This decision is a strong message to health care providers that just because a regulatory requirement is not expressly tied to or made a prerequisite of reimbursement does not mean that violation of that regulation cannot lead to liability under the False Claims Act. Whatever the governmental payer considers a "material precondition" to its obligation to pay for services rendered could form the basis for FCA liability. Given the draconian penalties under the FCA – civil penalties up to \$11,000 per false claim and up to three times the dollar value of each false claim – this decision raises the stakes on providers' compliance programs. Given the open-ended nature of the court's rationale – how can providers know what's material to a government payer's decision to pay a claim? – this decision also broadens to an unclear extent providers' potential for False Claims Act liability.

Peter J. Martin, Esquire, is a partner in the Worcester office of Bowditch & Dewey, LLP, his practice concentrating on health care and nonprofit law.

### society snippets

# 2015 Annual Business Meeting

Worcester District Medical Society, Massachusetts Medical Society 2015 Community Clinician of the Year Recipient – Matilde Castiel, M.D.





Left Photo: Jose Lemos, PhD, Nominator Matilde Castiel, MD, Award Recipient George Abraham, MD, Chair of Awards Committee

Right Photo: Matilde Castiel, MD, Award Recipient

#### **50 Year Anniversary Members**





Left Photo: Frederic Baker, MD, *President* Diane Messersmith, MD, accepting for Murray Janower, MD

Right Photo: Frederic Baker, MD, *President* Dorista Goldsberry, MD

### **25 Year Anniversary Members**



Jennifer Daly, MD, Annie Abraham, MD, Aaron Mendel, MD, Stephen Smith, MD, Lynda Young, MD and Robert Terrill, MD

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(Front Row) Joyce Cariglia (Second Row) *Past Presidents,* Jane Lochrie, MD, Edward Amaral, MD, Leonard Morse, MD, Paul Steen, MD, Lynda Young, MD, Thomas Rosenfeld, MD, Robert Sorrenti, MD (Back Row) *Current President*, Frederic Baker, MD, *Past President*, George Abraham, MD

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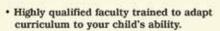
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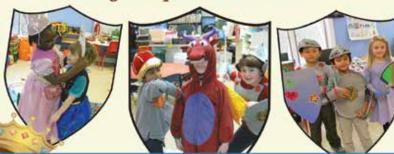
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### 25th national doctors' day - march 30, 2015

The following articles, "Muzzling docs bad medicine" and "Worcester doctors lead push to target gun 'gag laws'" (page 25) appeared in the March 24 and March 30 issues of the Telegram & Gazette.

This effort is the result of the Worcester District Medical Society's resolution, Preserving Free Speech and Confidentiality in the Physician-Patient Relationship, which was adopted by the Massachusetts Medical Society (MMS) House of Delegates, recommending that the MMS dedicate Monday, March 30, 2015, known as Doctors Day, to the recognition of the basic principles of confidentiality and free speech in the doctor-patient relationship.

The Worcester District Medical Society (WDMS) extends its appreciation to the authors of the resolution, Dr. Michael Hirsh, Dr. Leonard Morse, Patrick Lowe and Patrick Alvarado, and also to WMDS President Dr. Frederic Baker, WDMS Vice President Dr. James Broadhurst, and to the Massachusetts Medical Society for its efforts in raising awareness about gun safety and the right of physicians to discuss the subject with their patients.

# Muzzling docs bad medicine

Richard S. Pieters, M.D., Frederic Baker, M.D. and Michael Hirsh, M.D.

In 1991, President George Bush proclaimed March 30 as National Doctors Day, to salute physician leadership in the "prevention and treatment of illness and injury." Physicians honor the designation; few professions have an annual national day of recognition acknowledging their work.

This year, however, on the 25th anniversary of National Doctors Day, physicians across the commonwealth are taking the day to raise awareness about gun safety, and specifically, the right of physicians to discuss the subject with their patients.

At issue is a 2011 Florida law making it illegal for physicians to ask patients if they own a firearm or to record information about gun ownership in a patient's medical record. Regarding it as an intrusion into the physician-patient relationship, pediatricians in the state, backed by medical societies, sued to block the law, and it was initially struck down.

The state appealed, however, and a three-judge panel of the U.S. Court of Appeals for the 11th Circuit upheld the law in a 2-1 decision, which declared that the law regulates physician conduct "to protect patient privacy and curtail abuses of the physician-patient relationship." A provision of the law does allow inquiries and records if the physician "in good faith believes that this information is relevant to the patient's medical care or safety, or the safety of others."

Florida physicians, stunned at the ruling and believing the issue of "relevance" too weak to assure compliance with the law, have petitioned for a rehearing before the full court. The stakes are high: if the court's decision is again upheld, similar laws now pending in nearly a dozen other states are likely to be passed.

This is not just a bad law; it's bad medicine.

The exercise of an unrestricted patient interview is the physician's best approach to good patient care. To declare that asking patients about gun ownership and talking about gun safety is an abuse of the physician-patient relationship is illogical and strains the definition of common sense.

Physicians ask patients about many topics affecting their health, and we hope their responses are forthcoming and truthful. Smoking, substance abuse, alcohol use, driving ability, eating and exercise habits, and sexual activity are among those behaviors that affect health. Our obligation as health care providers compels us to ask about these subjects. All of them pose risks to health, and not only to the individual patient, but also to their loved ones and those around them.

Guns likewise pose risks: multiple studies show conclusively that guns in the home significantly raise the risks of homicide, suicide, and unintentional shootings.

That pediatricians are leading the fight for the right to discuss gun safety is appropriate. Research shows that firearm violence is among the leading causes of death for teenagers and young adults.

The health risks of guns to youth cannot be overstated. Statistics from the U.S. Centers for Disease Control, as reported by the Brady Campaign, show that more than 2,600 children and teens up to 19 years of age die from gun violence in an average year. Additional research indicates that on average 20 children and adolescents are hospitalized each day due to firearm injuries.

Tragic shootings like those at Columbine, Colorado and Newtown, Connecticut grab our attention and inevitably raise calls for more action. Yet since the shootings at Sandy Hook School in Newtown in 2012, 104 additional school shootings in America – 59 of them in grades K through 12 – have occurred.

Youth are not the only victims, of course. We must recognize that America is filled with guns. Ownership estimates range anywhere between 100 million and 300 million nationwide, and in Massachusetts alone, the U.S. Bureau of Alcohol, Tobacco, Firearms and Explosives has accounted for 32,682 registered weapons.

The final outcome in Florida will have national implications for how physicians care for the patients. It may also create a terrible precedent: If discussions about gun safety are prohibited, what topics might next be banned?

Doctors Day acknowledges our leadership in health care. The centerpiece of that care is the physician-patient relationship; it is where problems are discovered, diagnoses are made, care is delivered, and prevention begins. Health care works best when physicians and patients engage in confidential, private, open and free discussions. Restricting this exchange to any degree only prevents physicians from practicing good medicine – and denies patients, particularly our children – from getting the care they deserve.

Dr. Pieters, a radiation oncologist, is President of the Massachusetts Medical Society. Dr. Baker, a family physician, is President of the Worcester District Medical Society. Dr. Hirsh, a pediatric surgeon, is medical director of the Worcester Public Health Department and established the City's Goods for Guns program in 2002. All three physicians practice at UMass Memorial Medical Center.

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# Worcester doctors lead push to target gun 'gag laws'

Susan Spencer, Telegram & Gazette Staff



From left, Dr. Michael P. Hirsh of UMass Memorial Children's Medical Center, and Patrick Lowe, third-year medical student at UMass Medical School. (T&G Staff/PAUL KAPTEYN)

Do you smoke? How much alcohol do you drink a week? Do you use a seat belt?

These are questions that physicians routinely ask their patients. They're intended to raise awareness of health risks and allow doctors to advise patients on how they can improve their health and safety.

How about, Do you have a gun in the home?

If you're a health care practitioner in Florida, under a law passed in 2011, asking that question or entering any mention of gun ownership into a medical record could land you in trouble with your licensing board.

The law was challenged by several medical societies, spearheaded by pediatricians and family physicians, but was upheld in July by a 2-to-1 majority on a three-panel federal appeals court. The physician plaintiffs have requested a full-panel court review.

But 12 other states, mostly in the South, have similar legislation pending.

The prospect of government interference into what doctors can discuss with their patients has sent chills through the health care profession nationwide. In the Feb. 24 issue of the Annals of Internal Medicine, eight health professional organizations and the American Bar Association issued a call to action on firearm-related injury and death. Among the priorities is fighting physician "gag laws."

The Massachusetts Medical Society's House of Delegates passed a resolution opposing any attempt by government to interfere with a physician's right to free speech as means to improve patient health, and

are dedicating national Doctors Day on Monday to recognition of the basic principles of confidentiality and free speech in the doctor-patient relationship.

The push for the medical society's resolution came from Worcester, sponsored Dr. Michael P. Hirsh, UMass Memorial Medical Center pediatric surgeon and medical director of the city's Division of Public Health; Dr. Leonard Morse, former Worcester Commissioner of Public Health, and University of Massachusetts Medical School students Patrick P. Lowe and Patrick Alvarado.

"An unsecured weapon in the home is a public health danger," said Dr. Hirsh. "We want to be able to talk about it."

He said that having a gun in the home increases the risk of homicide five times; the risk of suicide by eight times; and the risk of "femicide" – killing women – 11 times.

Dr. Hirsh said that the most important questions to ask pediatric patients' family are: Do you use car seats and seat belts? Do you have smoke detectors? Is there a gun in the home?

If the family does have a gun, Dr. Hirsh said he would ask how it is stored and whether the ammunition is removed properly.

He also asks parents if they think the kids know where the gun is. In one study, even when parents said their children didn't know, 90 percent of the time the kids found the gun right away.

"We can't just be taking rescue care of patients," Dr. Hirsh said about the need to raise preventive questions with patients.

"This restriction on the doctor's judgment and their First Amendment rights is what makes this law so onerous. We have to teach doctors how to get into their patients' heads. It starts with freedom of speech."

Dr. Hirsh said that Mr. Lowe and Mr. Alvarado quickly grasped in their training that part of the doctor-patient relationship is to establish clear-cut preventive medicine questioning in all aspects of medical care.

The students asked if they could advance the notion, in light of threats to that relationship by laws on gun questions, so they drafted the resolution.

Mr. Lowe, of Northboro, a third-year medical student who is also pursuing a Ph.D. in biomedical sciences, said: "We saw this was pretty important from an advocacy perspective. ... A patient is twice as likely to quit smoking if their doctor asks about it. This is kind of a similar scenario."

Mr. Lowe said he is leaning toward practicing emergency medicine, a more episodic form of medical treatment than primary care. The

## 25th national doctor's day – march 30, 2015



From left, Dr. Michael P. Hirsh, division chief of pediatric surgery and trauma at UMass Memorial Children's Medical Center, and Patrick Lowe, third-year medical student at UMass Medical School. (T&G Staff/PAUL KAPTEYN)

primacy of the doctor-patient relationship and open communication in that setting is equally important, he said.

"You see the firsthand effect of gun violence in the ER. Even in the ER you go through a slew of prevention questions. These issues are pretty broad and applicable across all specialties."

Mr. Lowe added that there was no hidden agenda to infringe on anyone's Second Amendment right to have guns.

"The agenda we're coming at in this is promoting health and safety," he said.

"The evidence is just overwhelming," said professor David Hemenway about the health risks of access to guns. Mr. Hemenway is an economist and director of the Harvard Injury Control Research Center at Harvard T.H. Chan School of Public Health.

More than 32,000 deaths per year occur in the U.S. as a result of fire-arm-related violence, suicides and accidents, the highest rate by far among industrialized countries.

Suicide ranks as the 10th leading cause of death in the U.S. and in more than half the cases, over 19,000, the suicide was committed with a gun. Firearm-related suicide far outnumbers the roughly 11,000 annual gun murders.

Approximately 300 million guns are owned by U.S. civilians, in a country with a population of 320 million. The U.S. is also No. 1 in the developed world in private gun ownership.

"If you care about kids' health, then you have to care about what is most dangerous to children. It's injuries and violence," Mr. Hemenway said. "In the same way, physicians should be asking about guns because they're very dangerous to children."

Mr. Hemenway said that children die from accidental shootings by other children, and firearms are the deadliest factor in suicide attempts. Some 90 percent of suicide attempts with a gun end in death, compared to 2 or 3 percent of methods such as pill overdoses.

And while gun lobbyists argue that having a gun deters violent crime, a study published in September by Dr. Michael Siegel at Boston University School of Public Health found that states with higher rates of gun ownership experienced higher rates of firearm homicide between people who knew each other. There was no significant relationship between gun ownership and rates of homicide by strangers.

The executive director of Gun Owners Action League in Northboro did not answer requests for comment. Neither did the director of public affairs for the National Rifle Association in Virginia.

Arguments that allowing doctors to inquire about guns in the home and record the information in a patient's medical record would allow the government to build a registry of gun owners are "fear mongering," according to Dr. Hirsh.

"This is HIPAA-protected information; I can't reveal that," he said, referring to the 1996 Health Insurance Portability and Accountability Act

Dr. Frederic Baker, a Holden family medicine physician and president of the Worcester District Medical Society, said that maintaining the right to talk about gun safety wasn't a political statement.

"This is a relationship that's based on mutual trust and respect," he said. "We ask about sexual practices, addiction ... Where would it end? You can't really restrict that speech. You would end up being mute on a subject that's so critical."

Dr. Baker sees patients of all ages, from children to the elderly. Among his patients are people in the military or law enforcement, hunters and others with guns. He said people always have the right not to talk about guns in the home.

And with the gun violence death toll at 88 people per day in the U.S., costing \$174 billion a year, Dr. Baker said, "This is not irrelevant."

He continued: "To restrict that ability to ask that question, you're doing a great disservice. If you can't have a conversation (with your doctor) about things that affect safety and health, who can you have that conversation with?"

New England states haven't seen formal proposals for gun privacy laws similar to Florida's, although Dr. Hirsh said that the closest discussion he's heard of has been in New Hampshire.

State Sen. Ryan C. Fattman, R-Webster, whose district includes communities where gun owners' rights are a top concern, commented in an email: "If anyone proposed a law like this in Massachusetts, I believe that the personal privacy of a patient is paramount and needs to be respected. Patients should not be required to divulge information they are not comfortable sharing. If a doctor is concerned about their patient for any reason, they should take the appropriate steps to address it within the confines of the law and their professional judgment."

Dr. Hirsh said he hoped that health professionals and gun lobbyists could find common ground to work toward reducing risks of gun availability, such as improving access to mental health treatment and screening for mental health risks or suicidal tendencies in gun background checks.

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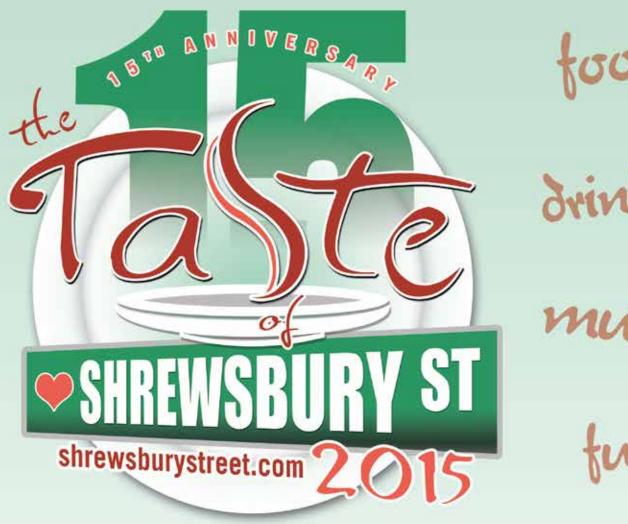


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