

# Embracing the ‘new normal’

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Since 1971, when President Richard M. Nixon announced the “war on cancer” with the signing of the National Cancer Act, we have seen an increase of 300% in the number of survivors, which is now reaching more than 12 million in the United States, according to the Centers for Disease Control. By 2020, that number will likely approach 20 million. Investment in research, early detection, and prevention has contributed to making these numbers a reality, and community-based oncology centers have played a critical role in delivering quality care and improved survival numbers based on the findings of that research. Therefore, it is logical that these same networks of community-based providers that have helped create survivors now help take the next step in addressing the needs of cancer patients on their journey to a life beyond cancer.

Newer, more targeted treatment agents have made it possible to view cancer as a “chronic disease”—a disease, like diabetes and cardiovascular diseases, that can be controlled for variable lengths of time, but may not be “cured.” Associated with these life prolonging therapies, however, are the challenges of ongoing care and the associated costs, and therapy-related toxicities, which translate into the need for patients to receive focused clinical, financial, social, spiritual, and emotional support, and to be educated about their new needs and circumstances.

Unfortunately, as patients near or complete their treatment phase, they commonly describe feelings of abandonment and emotional turmoil in addition to the effects of ongoing physical toxic-

ities and the ripple effects of treatment. They too often face financial crises at the end of their treatment, altered and strained relationships or a broken family, loss of employment, and the challenges of finding what many describe as their “new normal” as a survivor.

Survivorship care needs to be targeted and personalized; it must address the long-term needs of survivors, their transition back to their primary care providers, and the management of comorbidities that may have been created by their treatment, pre-existing, or are simply part of the reality that most cancer patients are over 65. Indeed, community oncologists should strive to understand the “molecular basis” equivalent of the challenges of survivorship so that it can be managed as effectively and efficiently as their patient’s cancer. Who better to assist the survivor than the team of providers who make this journey possible?

Therefore, we are pleased to initiate a new monthly series for COMMUNITY ONCOLOGY that will focus on issues relating to cancer survivorship. It is intended to equip and inform those who practice in the community and who care about their patient’s journey to a life beyond cancer. We hope too, that it will become a platform for sharing and exchange where we welcome our community’s input.

In the course of this series on survivorship, we’ll examine topics that address the continuum of survivorship. We’ll consider emerging concerns about survivorship and new opportunities for improving care and balance those discussions with an examination of the financial, psychological, and health-related quality-of-life implications of survivorship. We’ll look at new models of survivorship care to better understand the challenges a survivor will face along the path from diagnosis and treatment (eg, distress) and surveillance (eg, fear of recurrence), to long-term well-being (eg, establishing a

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## A survivor speaks

**‘The moment cancer becomes personal is the moment a life changes.’**

Nothing can prepare you for cancer treatment and nothing can prepare you for its aftermath.

Despite the advances in cancer treatment, increased cancer advocacy, and the examples of prominent survivors such as the figure skater Scott Hamilton or Good Morning America’s Robin Roberts, the moment cancer becomes personal is the moment a life changes.

I had that moment in 1998. At 43, I was diagnosed with a locally advanced breast cancer. Two years later, I finished treatment and landed “on the other side” in a body that didn’t look, feel, or function in the way it had before. It’s only in retrospect that I completely understand how difficult that transition was for me and how difficult it could be for future survivors if key support systems are not in place.

Discovering that I was not alone in finding the path back toward health certainly helped. But some advance preparation about the subsequent effects of radiation, the possibility of lymphedema, or the intensity of the cognitive difficulties brought on by hormonal therapies would have gone a long way. Some 10 years later, I was talking to a researcher who said, “oh, tamoxifen is a very difficult drug in younger women.” That was all I needed to know. The simple truth.

In lieu of readily accessible information, I coped in ways that were emotionally significant to me *and* healthy. I participated in a 60-mile Avon walk. I started cycling and added up the miles until I found myself cycling passes in the Bicycle Tour of Colorado. I talked with women from Saudi Arabia about delayed breast reconstruction. I talked with other survivors. I found my community. Survivorship became a passion.

Today there’s hope for all survivors, thanks to the groundbreaking work and advances in the field of survivorship. For example, the National Coalition of Cancer Survivorship; Lance Armstrong’s Livestrong, through its Survivorship Center of Excellence Network; and the National Cancer Institute, through its Office of Cancer Survivorship, are working to ascertain the long-term financial, psychosocial, spiritual, and medical needs of survivors and to define standards of care. Now the Life Beyond Cancer Foundation has developed a new program, the Providers for Survivors Network, to ensure that those elements filter into local communities patient by patient, community by community, as personalized survivorship care that is based on a seamless plan spanning diagnosis, treatments, the crucial transition to survivorship, and life beyond that.

—Jody Schoger

*Ms. Schoger is a freelance writer and creator of Women With Cancer, a blog that address health-care issues for women cancer survivors at <http://womenwocancer.blogspot.com/>. She served on the Life Beyond Cancer Foundation’s retreat planning committee in November 2010 and 2011.*

“new normal”) and end-of-life matters. Fertility preservation, the prevention of secondary disease and recurrence, pain management, and palliative care will also be included in the long-term considerations.

From a policy perspective, we will highlight the American Society of Clinical Oncology’s treatment plans and new program, Journey Forward<sup>1</sup>; the American College of Surgeons,<sup>2,3</sup> requirement for transition care plans; and the National Coalition for Cancer Survivorship’s<sup>4</sup> treatment plans as tools that have been developed for patients and providers to improve outcomes, better coordinate referrals and care, and establish treatment plans and surveillance for recurrence. Our intent is to help you implement a survivorship planning program for your patients and to gain insight from the experiences of other providers who are adapting their local practice setting as well.

The survivor’s senses of abandonment, loneliness, and fear—especially of recurrence—are among the issues documented in the Institute of Medicine’s 2005 report, *From Cancer Patient to Cancer Survivor: Lost in Transition*,<sup>5</sup> though others were noted some years earlier in the 2001 report by the President’s Cancer Panel, *Voices of a Broken System: Real People, Real Problems*.<sup>6</sup> Today, thanks to the efforts of advocacy organizations and the professional community and government agency thinking on survivorship, we have a more encompassing, evolving set of initiatives, guidelines, and resources that address many of the nontraditional medical issues, such as the aforementioned financial, spiritual, emotional, psychosocial well-being.

It is clear that the changes in the US health-care system and funding will add a degree of opportunity and challenge. The Affordable Care Act offers opportunities for access to services, which means that those who had lost coverage for preexisting conditions now have options for coverage. What impact will those opportunities have on survivors? There remain many other unanswered questions, so we will look closely at how the current health-care reform legislation, implementation status, and variability in state programs affect survivorship. In keeping apace with this volatile health-care scenario and the demands of caring for an aging survivor population, we will explore the need to use new technologies and develop a sustainable workforce by drawing on resources such as patient navigators, *promotoras*, and community health workers to fill potential gaps in care.

Much has been written about the waste in our delivery system and the failure to link the true costs of health care, such as tobacco abuse, obesity, lack of exercise, and end-of-life care, to reimbursement policy. Irrespective of current or future government administrations, the market forces are pushing our health-care system toward evolu-

tionary change. The country's huge budget deficit is hastening the pace of innovation and change to streamline efficiency and productivity as we face cuts in entitlement programs in Medicare and Medicaid. Such policy and economic challenges will define how we address survivorship from the perspective of the patients and their families and the costs that such efforts entail.

As our ultimate goal is to improve the journey of cancer survivors, we will also address physician-patient communication, how to discuss end-of-life planning and choices with patients, hospice care, and legal and ethical concerns. Our role is to guide the health of our patients—which includes treating survivorship as a lifestyle and helping patients and their families plan for it from the moment of diagnosis. Cancer should be seen as a chronic condition and, for the growing majority, not an imminent terminal illness. To this end, we'll invite a survivor to write a brief complementary perspective on each month's topic so that we remain focused on the survivor and his or her needs (see sidebar).

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# FDA issues new rule on drug shortages

Reported by Alicia Ault

The Food and Drug Administration (FDA) has announced that it would require some manufacturers to give the agency early warning of an imminent drug shortage.

The agency made the announcement on December 15, 2011, as a Senate committee held a hearing the continuing drug shortage problem. It issued an interim final rule in response to President Obama's October 31 Executive Order asking the agency to use its existing authority to address the shortage issue. The rule would require manufacturers who are the only suppliers of a product "to report to the FDA all interruptions in manufacturing of products that are life supporting, life sustaining, or intended for use in the prevention of a debilitating disease or condition," according to a press release from the Department of Health and Human Services.

Dr. Sandra Kweder, deputy director of the FDA's Office of New Drugs, said at the Health, Education, Labor and Pensions (HELP) committee hearing that the agency has been busy since the October 31 order, among other things, reminding drug makers of their legal duty to report, in some instances, impending supply problems. She noted that the agency used to receive about 10 notifications a month of a potential shortage, and that between late October and mid-December, it had received 61 notifications. The agency has monitored 220 shortages since January 2011, and has prevented 96, she said.

Dr. Kweder said the agency had averted shortages by helping manufacturers get supplies of critical ingredients, by helping them change manufacturing processes, or by going to competitors and encouraging them to ramp up production of the drug that is in short supply. She noted that the FDA had recently worked with generic drug maker Teva to get its doxorubicin production online again, and had also approved Pfizer as a new maker of that chemotherapy drug.

The General Accounting Office (GAO) issued a new report at the hearing that urged Congress to require all manufacturers to report potential supply

issues to the FDA. "Because the FDA usually doesn't know about a shortage until it is well under way, the agency's approach to managing drug shortages is predominately reactive," said Marcia Crosse, director of health care at the GAO.

The GAO found that the agency does not maintain a database on shortages, which means it can't track trends or create effective strategies, said Ms. Crosse. The agency has the power to expedite reviews of generic drug applications, but currently has a backlog of 8,000 applications, said Ms. Crosse. Several Republican members of the Senate HELP committee questioned whether the agency was doing all it could to ease that backlog. Ms. Crosse said that the FDA had expedited hundreds of applications, but that it could not say whether any were completed in time to help resolve any particular shortage.

Sen. Richard Blumenthal (D-Conn.) suggested that some of the shortages might be owing to a lack of competition in the generic injectable industry. Data presented by the market research company IMS Health shows that more than 82% of the products in short supply over the last 5 years were generic injectables. "I will be proposing more aggressive measures that are necessary to crack down on what appear to be anticonsumer practices," said Sen. Blumenthal, a former attorney general of Connecticut. "The shortages are creating a public health menace," he said, adding that he was considering whether to direct the Department of Justice or the Federal Trade Commission to investigate what he called "astonishing and appalling mark-ups" for drugs in short supply.

The generic industry responded with a new initiative, which it announced at the hearing. The Accelerated Recovery Initiative includes manufacturers who represent 80% of the generic injectable market. They are proposing to provide more timely assessments of shortages and "establish practices that allow for potential, voluntary production adjustments to lessen or eliminate the impact of a current shortage," according to testimony by Ralph Neas, president and CEO of the Generic Pharmaceutical Association. The initiative has to be approved by the Federal Trade Commission and the Department of Health and Human Services, said Mr. Neas.