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ABC NEWSLETTER

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2010 #44 **December 3, 2010**

INSIDE:

Senate Fails to Muster Votes to Repeal New 1099 Rule

The Senate, in two votes on Monday, failed for the second time this fall to do away with a controversial provision of the healthcare reform law that would expand 1099 form reporting for for-profit and non-profit companies, including blood centers.

The Senate voted on two competing amendments. The counts were 61-35 on Sen. Mike Johanns' (R-Neb.) amendment and 44-53 on Sen. Max Baucus' (D-Mont.) amendment. The chamber needed 67 senators voting in the affirmative to garner the two-thirds majority necessary to move forward with consideration of the amendments.

Though Capitol Hill observers don't expect the issue to go away, repealing the provision will probably take a stronger amendment that contains a mechanism for making up the $19 billion in revenue the requirement is expected to generate. Some Democrats objected to Sen. Johanns' amendment because it would have countered the loss of revenue with unobligated funds. That would have given the Office of Management and Budget (OMB) director discretion to determine which funds would be used to pay for the repeal. Some Republicans did not care for Sen. Baucus' amendment because it did not identify an offset and therefore would have increased the deficit.

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Blood Centers' Roles in Healthcare Reform Unclear

Various federal agencies are working to implement the healthcare reforms passed this spring, but it remains to be seen what the changes will mean for blood centers and other providers, according to the speaker at a webinar presented by the American Hospital Association (AHA) on Tuesday.

John R. Combes, MD, the president and COO of the AHA's Center for Healthcare Governance, said the implications of healthcare reform for blood centers and other providers have not yet been addressed by the Centers for Medicare and Medicaid Services (CMS) or other agencies that are working to implement the reforms. However, he did suggest a number of areas in which blood centers might play a role: helping hospitals reduce their waste and utilize their resources as

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OUR SPACE

By ABC CEO Jim MacPherson

Letters, We Get Letters*

Two of my recent editorials provoked some thoughtful responses.

On the issue of 24-hour hold (see *ABC Newsletter*, 11/5/10), one reader thought I was too hard on FDA's requirements for pre-approval data. He believed that the agency should request the additional data it needs to feel comfortable in approving a new product or process. I apologized to the colleague that I had not made it clear that much of the data FDA is requesting is already published in the literature. There is no argument when FDA needs additional data; instead, the issue is duplicating existing studies. The studies may not have been conducted exactly as FDA usually requires, but for products that have safely been used for more than 20 years in Europe and elsewhere, it seems excessive to ask that studies be repeated at the costs of tens of millions of dollars. The colleague agreed.

On my wistful and tongue-in-cheek "Raise Your Prices" column (see *ABC Newsletter*, 11/12/10), another colleague noted that much of hospital resistance to the price of blood may be related to steady increases, especially over the last decade. It's an interesting point. In 1990 the typical red blood cell (RBC) distributed by an America's Blood Centers member cost a hospital about $90. By 2000, that cost had risen to $100, but by 2009 the price had doubled to $200. (All of my figures are in 2009 dollars, adjusted for medical inflation, which means the price of blood has doubled in 20 years, when accounting for inflation.) Clearly, the driving force for such cost increases were safety measures, such as the introduction of genetic testing for HIV, hepatitis C, and West Nile Virus; leukoreduction; TRALI measures; Chagas testing; and more. But from a hospital's perspective, an RBC to treat blood loss/anemia in 2010 at $200+ is not much different than a 1990 RBC at less than half the cost. It is safer; the risks to patients have declined. But does that translate into decreased hospital costs? There's not much data to support that contention. At the same time, costs for other generic drugs and medical devices hospitals buy have actually decreased. It would be speculation to say this is how supply-chain managers view blood, but it is a valid perspective.

*An homage to "The Perry Como Show" of the 1950s and '60s

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The *ABC Newsletter* (ISSN #1092-0412) is published 46 times a year by America's Blood Centers® and distributed by e-mail.

ABC is an association of not-for-profit, independent community blood centers that helps its members provide excellence in transfusion medicine and related health services. ABC provides leadership in donor advocacy, education, national policy, quality, and safety; and in finding efficiencies for the benefit of donors, patients, and healthcare facilities by encouraging collaboration among blood organizations and by acting as a forum for sharing information and best practices.

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(Residents, Fellows and SBB Students: $120)
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To The Editor: It's All About Grandma

One of my grandmother's favorite sayings was, "When they say it's not the money, it's the money." This took on new meaning for me after I read some recent articles comparing the risks and benefits of pooled platelet concentrates derived from whole blood buffy-coats (PBP) with those of single donor, apheresis platelet concentrates (APC). The Nov. 5, 2010, issue of the *ABC Newsletter* cited an article by Stephen Thomas, PhD (Ambient overnight hold of whole blood prior to the manufacture of blood components. Transfus Med 2010 Dec; 20 (6): 361-8), with discussion by Jim MacPherson in his weekly (always interesting) "Our Space" column. Mr. MacPherson stated that PBPs were an "effective and safe product for patients" and that most developed countries had been using them for decades. He also indicated that the entire country of Canada had recently switched to PBPs.

In 2008 Nancy M. Heddle and coworkers from McMaster University in Canada published an article regarding the safety and efficacy of PBPs versus APCs (Transfusion 2008; 48:1447-58). They compared factors such as posttransfusion increment in platelet count, incidence of alloimmunization, and refractoriness and incidence of transfusion reactions. They concluded that they could find no clear evidence that APCs were a superior product.

Interestingly, none of the articles cited above made any mention of the relative risk of disease transmission between these two components. It is hard to imagine that any comparison of the risks of transfusion of blood components would fail to consider the ever-present hazard of transfusion-transmitted disease. Might this simply have been an oversight? Not likely, since these authors are too knowledgeable for that to have occurred. Was it instead because of what Grandma said? Actually, Mr. MacPherson did state that PBPs are "easy and cheap to make."

But reliance on PBPs increases donor exposure by a factor of four to six. Is this important and is blood really so safe that we can willy-nilly expose patients to as many blood donors as we choose? Anyone who lived through the AIDS epidemic of the 1980s and the era of transfusion-associated hepatitis prior to 1990 would have to have an awfully short memory to think that transmission of disease should not remain at the top of the list when considering transfusion alternatives.

> **I am sure that the report by Ms. Heddle and associates – which compared risks and benefits of PBPs versus APCs but avoided mention of disease transmission as a potential hazard – went a long way toward justifying Canada's switch to PBPs. I am concerned that Mr. MacPherson's article, by leaving out discussion of the one and only clear benefit of APCs, could obscure the real focus of this debate and help foster a move in our own country to lift our vigilance toward minimizing disease transmission from transfusion in the name of cost savings. Pooled platelet concentrates harvested from whole blood, whether by the buffy-coat or platelet-rich plasma method, are not only old fashioned, they are archaic.**

My grandmother had another favorite saying: "Cheap is cheap." In other words, you get what you pay for. Of course, all of what I have said would be rendered moot if pathogen inactivated platelet concentrates were to become a reality. Nevertheless, the increased cost of this product could once again serve as a deterrent to its widespread acceptance.

Many people think that President Bill Clinton coined the term "Don't ask, don't tell." I think that it was actually blood bankers who invented this concept. We don't ask patients what they want, and we don't tell them what they'll get. This is contrary to the practice in other fields of medicine where full disclosure of risks and benefits of therapy and complete discussion of the available alternatives is the norm (and

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Letter to the Editor (continued from page 3)

really a requirement). There is no patient in his or her right mind who would knowingly choose to multiply donor exposure unnecessarily. No parent would choose to expose his or her child to four to six times the number of potentially risky donors when giving consent for transfusion support. Grandma really knew what she was talking about, and recognizing the wisdom of her words can allow us to make thoughtful decisions regarding transfusion alternatives without being misled by discussions which avoid the real issues in motivating our choices.

Dennis Goldfinger, MD
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Mr. MacPherson responds: Dr. Goldfinger is correct that pooled platelets increase donor exposure and therefore theoretical risks to patients. The risks of what we know about now are generally considered low enough that they are of decreased concern to many physicians that order blood for their patients. But real and theoretical threats from bacteria, Chagas, Babesia, Dengue, etc., continue to drive a push toward pathogen activation for all platelets – pooled or apheresis. Dr. Goldfinger is also correct that costs (along with low risk) are driving another look at pooled vs. pheresis platelets. But it is hospitals that are charged with patient care that every day examine risk-benefits in patient therapy, and it is they (not blood providers) that are driving such decisions.

Effort to Repeal 1099 Requirement Fails (continued from page 1)

Section 9006 of the Patient Protection and Affordable Care Act – several lines buried in the 2,409-page document – mandates that, starting in the calendar year 2012, both nonprofit and for-profit companies will have to issue 1099 tax forms not just to contract workers, but also to any individual or corporation from which they buy more than $600 in goods or services in a tax year. The 1099 forms are mailed at the end of January for the preceding year. Mostly, the forms are used to document income, other than wages and salaries, for individual workers. Freelancers receive them each year from their clients, and businesses issue them to the independent contractors they hire.

> **In early November, America's Blood Centers urged its members to help it repeal the provision, which would be quite burdensome for blood centers. For example, a blood center that bought copy paper or office supplies from a local distributor would have to send the supplier a 1099 form at the end of the year if the total purchases exceed $600.**

The amendments voted on Monday were attached to a larger food safety bill, which overcame a procedural hurdle to move forward by a vote of 69-26 shortly before the vote on the amendments.

"There are two big differences between our two amendments," said Sen. Baucus before the vote. "First, my alternative is especially friendly to small businesses. It takes extra measures to permit the IRS to waive certain duplicative reporting requirements for small businesses that use credit cards to pay their bills. Second, our two versions differ about paying for the change. The alternative offered by my colleague from Nebraska would give the unelected director of OMB unprecedented authority to slash spending, all on his own. The Johanns alternative would thus abdicate Congress's responsibility over the

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