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January 12, 2012

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WO 2200
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Silver Spring, MD 20993-0002

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RE: Citizen Petition — Docket Number FDA-2011-P-0923

Dear Drs. Hamburg and Shuren,

Public Citizen, a consumer advocacy group representing more than 250,000 members and supporters nationwide, wishes to supplement its December 21, 2011 petition to the Food and Drug Administration (FDA) (docket number FDA-2011-P-0923).

More than eight months ago, in April 2011, investigators conducting a large randomized, controlled, multicenter study funded by the National Institute of Neurological Disorders and Stroke (part of the National Institutes of Health [NIH]) stopped enrolling subjects earlier than planned. The study was designed to evaluate whether there was a benefit to implantation of a stent using the Wingspan Stent System with Gateway PTA Balloon Catheter (hereafter referred to as the Wingspan Stent System) in brain blood vessels of patients who had a recent stroke or transient ischemic attack (TIA) attributed to severe narrowing of such vessels. Subject enrollment in the study was stopped earlier than

planned because people treated with the Wingspan Stent System and appropriate medical treatment had a 2.5-fold higher risk of suffering a stroke or dying in the first 30 days after stent implantation than did comparable people treated with medical treatment alone. The action to stop subject enrollment was promptly reported to the FDA by the investigators.[1]

In addition, the study investigators were unable to find any evidence of benefit from treatment with the Wingspan Stent System after following trial subjects for up to 15 months. This study, known as the Stenting and Aggressive Medical Management for Preventing Recurrent Stroke in Intracranial Stenosis (SAMMPRIS) trial, is the only randomized, controlled study ever done with the Wingspan Stent System and thus provides the only reliable evidence of the relative safety and effectiveness of treatment with the Wingspan Stent System combined with medical therapy in comparison to treatment with medical therapy alone.[2] No such evidence was provided by the small pre-market Wingspan HDE safety study.

Since our December 21, 2011 petition to the FDA to ban the Wingspan Stent System, public statements by the current manufacturer of the device, Stryker, and by an FDA official suggest that the continued failure of the FDA to ban this dangerous medical device is related to some alleged lack of comparability between the subjects in the SAMMPRIS trial and the patients whom the Wingspan Stent System was intended to treat under the FDA's 2005 approval of the humanitarian device exemption (HDE) for this device. However, as our analysis shows, there was significant overlap in the clinical characteristics profile of subjects participating in the SAMMPRIS trial with the profile of subjects in the Wingspan HDE safety study and, more importantly, with the profile of the several hundred patients enrolled in post-approval registry studies who were treated with the Wingspan Stent System in accordance with the FDA-approved HDE indication between its approval in 2005 and the time frame of the SAMMPRIS trial.

The Wingspan Stent System was thought to be too dangerous to implant in any more subjects in the SAMMPRIS trial. It is likewise too dangerous to use in the hundreds of patients who have clinical characteristics that overlap with the clinical characteristics profiles of both the SAMMPRIS trial subjects and the population of patients eligible for treatment with this device under the FDA-approved HDE indication. Due to the FDA's unconscionable decision to delay withdrawal of the agency's approval of the Wingspan Stent System HDE, the continued use of this device exposes patients to an unacceptable risk of serious harm, including death.

I. Summary and Status of Original Petition

In our petition, we requested that the FDA, pursuant to the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 360h(e) and 360j(m) and 21 C.F.R. §§ 810 and 814.118, immediately:

(1) Withdraw approval of the HDE application, number H050001, for the Wingspan Stent System that was submitted by Boston Scientific Corp., because the

recently completed SAMMPRIS trial conclusively demonstrated that treatment of high-risk patients with intracranial artery stenosis with the Wingspan Stent System plus aggressive medical therapy provides substantially less benefit and causes significantly more harm (i.e., a 2.5-fold higher risk of stroke or death at 30 days post-intervention) in comparison to aggressive medical treatment alone,[3] and as a result:

(a) There is a lack of a showing of reasonable assurance that the device is safe under the conditions of use prescribed, recommended, or suggested in the labeling thereof;
(b) The device is ineffective under the conditions of use prescribed, recommended, or suggested in the labeling thereof; and
(c) There is not a reasonable basis from which to conclude that the probable benefit to health from the use of the device outweighs the risk of injury or illness, taking into account the probable risks and benefits of currently available alternative forms of treatment.

(2) Order Stryker, which bought Boston Scientific Neurovascular, to initiate a class I recall of all unused Wingspan Stent Systems because evidence of significantly increased risk of stroke and death in patients treated with this device, without evidence of any benefit compared to medical treatment without the stent.

We have not yet received a decision from the agency on our petition.

II. Supplemental Information

In a recent media report,[4] Stryker spokesperson Tamara Cutler, seeking to downplay the significance and relevance of the SAMMPRIS trial results with respect to the HDE application for the Wingspan Stent System, was quoted as stating the following in an email:

> The SAMMPRIS trial did not follow the current HDE indication for use; it focused on studying the treatment of severe intracranial atherosclerotic disease, early in the treatment lifecycle and with an aggressive treatment regimen and rigorous oversight of medication compliance.

Likewise, in another recent media report,[5] FDA spokesperson Michelle Bolek was quoted as making the following similar comments:

> Regarding the trials, the patient population studied for the trial that led to the Wingspan HDE approval is different than the one studied in the SAMMPRIS trial. SAMMPRIS patients were younger and had more stenosis and the lesions were in different locations.
>
> Also, patients had to have had a stroke in the Wingspan HDE study, and that was not necessarily the case in SAMMPRIS. Because of this, a direct

> comparison of the results of the 2 studies is limited by the differences in characteristics of the patients studied.

These comments are inaccurate, misleading, and irrelevant to the decision on whether to withdraw approval of the Wingspan Stent System HDE. First, the differences between the SAMMPRIS trial subject population and the small group of patients treated under the Wingspan HDE safety study are not substantial or important, nor do they justify discounting the significance of the SAMMPRIS trial results or giving greater weight to the data from the small, non-randomized, uncontrolled, pre-market approval Wingspan HDE safety study when assessing the safety and efficacy of this device.

Second, the FDA's focus should not be just on the small number of subjects enrolled in the Wingspan HDE safety study, but also on the entire patient population that is currently eligible for treatment with the Wingspan Stent System under the FDA-approved HDE indication — and therefore potentially at risk of exposure to serious harm if the Wingspan Stent System remains on the market. Indeed, a review of the FDA-approved HDE indication for the Wingspan Stent System shows that there is significant overlap between the clinical characteristics profile of subjects participating in the SAMMPRIS trial and the clinical parameters that make a patient eligible for treatment with the Wingspan Stent System under the FDA-approved HDE application. This overlap also can be demonstrated in a comparison of the clinical characteristics profile of subjects enrolled in the SAMMRPIS trial with the profiles of those patients who were treated with this device in the pre-market approval Wingspan HDE safety study and in the post-market approval registry studies. Failure to withdraw approval of the Wingspan Stent System allows continued exposure of a large group of patients (those eligible under the FDA-approved HDE indication) to an obvious high risk of proven severe harm.

A. The FDA-approved HDE indication for use of the Wingspan Stent System

The Wingspan Stent System is approved by the FDA for the following indication:

> The Wingspan Stent System … is indicated for use in improving cerebral artery lumen diameter in patients with intracranial atherosclerotic disease, refractory to medical therapy, in intracranial vessels with ≥50% stenosis that are accessible to the system.[6]

Of note, this indication does not stipulate a time interval between (a) the time when a patient experiences a neurologic event, such as a stroke or TIA, attributed to intracranial atherosclerotic disease and (b) the time when the patient is treated with the Wingspan Stent System. It also does not restrict use of the Wingspan Stent System to patients who had a stroke, patients above a certain age, or patients who have stenoses in specific intracranial artery locations.

Furthermore, the FDA-approved HDE indication does not specify the clinical parameters under which intracranial atherosclerotic disease is considered "refractory to medical therapy." As a result, physicians have significant discretion in determining whether a

patient presenting with a stroke or TIA attributable to intracranial atherosclerotic disease is "refractory to medical therapy" and thus meets the criteria for treatment with the Wingspan Stent System. For example, a patient presenting with his first stroke or TIA who is subsequently found to have a 90% intracranial artery stenosis (to which the stroke or TIA could be attributed) on angiography within a few days of neurologic symptom onset could be considered refractory to treatment if that patient had medically well-controlled hypertension and hypercholesterolemia and was taking only aspirin as antiplatelet therapy. Such a patient would be eligible for treatment under the FDA-approved HDE indication for the Wingspan Stent System. That patient would also fit the clinical characteristics profile of subjects enrolled in the SAMMPRIS trial, and therefore use of the Wingspan Stent System would expose him to unacceptable risk of harm and no prospect of benefit.

B. Clinical characteristics profiles of subjects treated in the pre-market approval Wingspan HDE safety study, the post-market approval Wingspan registry studies, and the SAMMPRIS trial

The pre-market approval Wingspan HDE safety study was very small, and it was reasonable to expect that the patient population treated with the Wingspan Stent System under the HDE following approval would encompass a broader range of clinical characteristics. Indeed, as discussed above, the language of the FDA-approved HDE indication clearly allowed for this broader eligibility for treatment with this device.

Therefore, in placing the SAMMPRIS trial results in appropriate context, the clinical characteristics profile of subjects in that trial should be compared not only to those of the subjects enrolled in the small pre-market approval Wingspan HDE safety study,[7,8] but also to those of patients treated with this device after approval, who were enrolled in the post-market approval registry studies (the U.S. Wingspan Registry[9] and the NIH Wingspan Intracranial Stent Registry Study [the NIH Wingspan Registry Study] [10]) and considered eligible for treatment with the Wingspan Stent System under the FDA-approved HDE indication.

The following is a summary comparison of published data regarding various clinical and demographic parameters for subjects in these studies.

History of stroke or TIAs and qualifying events for study enrollment: Not all patients enrolled in the Wingspan HDE safety study and registry studies had a prior history of stroke, making these populations comparable to the SAMMPRIS population in this respect.

- SAMMPRIS trial (N=451): 294 subjects (65.2%) presented with a stroke as the qualifying event, and 157 subjects (34.8%) had a TIA as the qualifying event. One-hundred-eighteen subjects (26.1%) had a prior stroke before the qualifying event.[11]

- Wingspan HDE safety study (total N=45): All subjects were reported by the FDA in its Summary of Safety and Probable Benefit for the HDE application for the Wingspan Stent System to have had a past history of stroke, although Table 5 indicated that only 43 subjects (95.6%) had a history of stroke.[12] The history of prior stroke also was not clearly described in the two published reports of this study.[13,14]

  Regarding the qualifying neurologic event leading to study intervention, Bose et al reported that 42 subjects (93.3%) had stroke as the qualifying event, and 3 subjects (6.7%) had a history of TIAs as the qualifying event.[15] However, in a separate report on a subset of 15 subjects enrolled at one study site in the Wingspan HDE safety study,[16,17] Henkes et al reported that for eight subjects the presenting symptoms prior to treatment with the Wingspan Stent System were recurrent TIAs. It is difficult to reconcile the data on qualifying events reported by Bose et al and by Henkes et al.

- U.S. Wingspan Registry (N=158): 90 subjects (56.9%) presented with stroke as the qualifying event. Data on a past history of any prior stroke was not presented.[18]

- NIH Wingspan Registry Study (N=158): 91 subjects (57.6%) presented with a stroke as the qualifying event, and 64 (40.5%) had a TIA or other event as the qualifying event. Data on a past history of any prior stroke was not presented.[19]

While only one-quarter of the subjects in the SAMMPRIS trial had a history of stroke prior to presenting with a qualifying event, 65% had a stroke and 35% had a TIA as their qualifying events. Moreover, a prior history of stroke was not required for enrollment in the NIH Wingspan Registry Study and does not appear to have been a requirement for enrollment in the U.S. Wingspan Registry. The percentages of patients qualifying for enrollment in the SAMMPRIS trial because of either stroke or TIA were very similar to the percentages seen in the registry trials, both of which only enrolled subjects who were considered eligible for treatment under the FDA-approved HDE indication for the Wingspan Stent System. Thus, with respect to presenting neurological history and qualifying neurological events, while there was some dissimilarity in the SAMMPRIS subjects in comparison to the subjects enrolled in the small Wingspan HDE safety study with respect to prior stroke history, there was significant similarity between the SAMMPRIS subjects and the HDE-eligible subjects enrolled in the two registry studies. This indicates that with regard to history of stroke the SAMMPRIS trial subject population accurately reflects the patient population currently considered eligible for treatment with the Wingspan Stent System under the FDA-approved HDE indication.

Interval between presenting qualifying neurologic event (stroke, TIA, or other) and intervention with the Wingspan Stent System: There is significant overlap between the SAMMPRIS trial, the Wingspan HDE safety study, and the two registry studies in terms of the interval between the presenting qualifying neurological event and intervention with the Wingspan Stent System.

- SAMMPRIS trial (N=451): The median time from qualifying event to randomization in the study was seven days, with an interquartile range of 4-16 days for the subjects who underwent intervention with the Wingspan Stent System. The time from the qualifying event to the actual stenting procedure in these subjects must have been slightly longer, because subjects were required to undergo the procedure within *three business days* of randomization, meaning the procedure could have been delayed up to *five days* post randomization.[20]

- Wingspan HDE safety study (total N=45): To be enrolled, subjects had to be at least seven days after any stroke. There was no reported time constraint regarding the time since the most recent TIA.[21]

- U.S. Wingspan Registry (N=158): The three published reports for this study do not provide any data regarding the time interval between the time of the qualifying neurologic event and time of intervention with the Wingspan Stent System.[22,23 ,24]

- NIH Wingspan Registry Study (N=158): The median time from qualifying event to stenting was 10 days, with a range of 0-275 days. Thirty-seven percent of subjects underwent stenting within five days of their qualifying event.[25]

Treatment with antiplatelet or anticoagulant medication at time of qualifying neurologic event and subsequently prior to Wingspan Stent placement: There is also significant overlap between the relevant studies with regard to antithrombotic treatment at the time of the qualifying event and subsequently prior to Wingspan Stent placement.

- SAMMPRIS trial (N=451): 286 subjects (63.4%) were already on antithrombotic treatment at the time of their qualifying neurologic event. All subjects were treated with aspirin (325 mg daily) and clopidogrel (75 mg daily) following enrollment and prior to the stenting procedure. Subjects assigned to the stenting group who were not taking clopidogrel at a dose of 75 mg daily for at least five days before the stenting procedure were given a 600-mg loading dose of clopidogrel between six and 24 hours prior to the procedure.[26]

- Wingspan HDE safety study (N=45): All subjects were taking some form of antithrombotic therapy at the time of their qualifying neurologic event. Of these, 38 (84.4%) were taking one or more antiplatelet medications (aspirin, clopidogrel, or ticlodipine), 19 (42.2%) were on anticoagulants (heparin or warfarin), and 12 (26.6%) were on a combination of antiplatelet and anticoagulant. All subjects received clopidogrel (75 mg daily for three days before the procedure or 225 mg on the day before the procedure) and aspirin (300 or 325 mg daily for three days before the procedure or 300 to 650 mg on the day before the procedure).[27]

- U.S. Wingspan Registry (N=158): Data regarding antiplatelet or anticoagulant medication use at the time of their qualifying neurologic event was not presented in the most recent report of this registry study.[28] However, the initial report by

Fiorella et al on the first 78 subjects enrolled in this registry indicated that only 59 subjects (75.6%) had a well-documented history of antiplatelet failure at the time of their qualifying event (stroke or TIA). All subjects were pretreated with antiplatelet agents (typically, both clopidogrel and aspirin, doses not specified) before undergoing the procedure.[29]

- NIH Wingspan Registry Study (N=158): Per the investigators, all subjects enrolled in the registry had to be on some form of antithrombotic therapy at the time of their qualifying neurologic event, but this was not specified further. All subjects were treated with aspirin (81-325 mg daily) and clopidogrel (75 mg daily) at least three days before the stenting procedure or were loaded with clopidogrel (300 mg) and aspirin (81-325 mg) within 24 hours of the procedure.[30]

A majority of SAMMPRIS subjects (63%) were on antithrombotic therapy at the time of their qualifying neurologic event and all were pretreated with such therapy before undergoing stent placement, both of which appear to be similar to the percentage seen in the U.S. Wingspan Registry subjects and the NIH Wingspan Registry Study subjects.

Degree of intracranial artery stenosis: The populations in the relevant studies do not differ significantly in terms of degree of intracranial artery stenosis.

- SAMMPRIS trial (N=451): All subjects had ≥70% intracranial stenosis; mean ±standard deviation (SD): 81%±7% for the control group and 80%±7% for the stenting group.[31]

- Wingspan HDE safety study (total N=45): Mean±SD: 74.9%±9.8%; median: 75.0%; range (max, min): 57%, 99%.[32,33]

- U.S. Wingspan Registry (N=158): The most recent report of this registry study indicated that the 158 subjects had 168 stenoses of 50-99%. Of these, the mean stenosis was 75.2% (no SD provided) and 115 stenotic lesions (68.5%) had ≥70% stenosis at the time of intervention, but further statistics were not provided.[34]

- NIH Wingspan Registry Study (N=158): Mean±SD: 77%±13%; 129 subjects (81.6%) had stenotic lesions ≥70%.[35]

With respect to the degree of intracranial artery stenosis, all subjects in the SAMMPRIS trial fell within the range of stenosis specified in the FDA-approved HDE indication. Also, the majority of subjects in the Wingspan HDE safety study and the two registry studies (68% and 82%) had a degree of intracranial stenosis that exceeded 70%.

Subject age: The age range for the various trials is comparable. Moreover, it would be highly unusual for the slightly older population studied in the HDE safety study to somehow be less likely to experience death or stroke within the first 30 days after stent

implantation (the main source of risk for the device as shown by the SAMMPRIS trial), making this distinction unlikely to be relevant.

- SAMMPRIS trial (N=451): Mean±SD: 59.5±11.8 for the control group and 61.0±10.7 in the stenting group.[36]

- Wingspan HDE safety study (N=45): Mean±SD: 66±8; median: 65; range (min, max): 47, 81.[37]

- U.S. Wingspan Registry (N=158): Mean: 62.7 (SD not reported); range (max, min): 33, 86.[38]

- NIH Wingspan Registry Study (N=158): Mean±SD: 63.9±12.6; percent over age 64: 51%.[39]

Although the age distribution was somewhat lower in the SAMMPRIS trial subjects in comparison to the Wingspan HDE safety study subjects, most of the SAMMPRIS trial subjects fell within the age range seen in the Wingspan HDE safety study subjects. Moreover, the age range for the SAMMPRIS trial subjects was very similar to that seen in the two registry studies.

Finally, the FDA cannot reasonably assert that the Wingspan Stent System is safe for a patient population older than the SAMMPRIS trial subject population. This is because the main source of risk in the SAMMRPIS trial was death or stroke within 30 days of the stenting procedure. If anything, older patients would be *more* likely to experience such adverse outcomes during or after a high-risk invasive intervention such as that required to implant the Wingspan Stent.

Other demographic and clinical parameters

Clinical parameter	Wingspan HDE safety study (N=45)[40]	U.S. Wingspan Registry (N=158)[41]	NIH Wingspan Registry Study (N=158)[42]	SAMMPRIS trial (N=451)[43]
Male sex	73.3%	60.1%	56.0%	60.3%
Ethnicity				
Caucasian	73.3%	NA	82.6%	71.2%
African American	0%	NA	NA	23.3%
Asian/other	26.7%	NA	NA	5.5%
Medical History				
Hypertension	91.1%	NA	NA	89.6%
Hypercholesterolemia/ hyperlipidemia	57.8%	NA	NA	88.0%
Diabetes	53.3%	NA	NA	46.3%
Angina/CAD	22.2%	NA	NA	23.5%

NA: not available

For these demographic and clinical parameters, there were, again, significant similarities between the SAMMPRIS trial subjects and those subjects enrolled in the Wingspan HDE safety study and in the two registry studies.

C. Summary discussion

The spokespersons for both Stryker and the FDA have attempted to downplay the significance and relevance of the SAMMPRIS trial results with respect to the HDE application for the Wingspan Stent System by raising concerns about dissimilarities between the clinical characteristics profile of the SAMMPRIS trial subjects and the profiles of patients whom the Wingspan Stent System was intended to treat under the FDA's 2005 approval of the HDE application for this device. Such arguments should be rejected for several reasons.

(1) The type of subjects enrolled in the SAMMPRIS trial — patients with ≥70% stenosis of an intracranial artery, who have had a recent stroke or TIA in the distribution of the stenotic lesion — were considered to be at the highest risk of suffering additional neurologic injury from a stroke and therefore were thought to be the subgroup of patients *most* likely to benefit from placement of a stent using the Wingspan Stent System in the sclerotic intracranial artery. It defies comprehension to assume that these subjects will not continue to be treated with the Wingspan Stent System if the product remains on the market under the current FDA-approved HDE indication.

(2) The pre-market approval Wingspan HDE safety study was very small, and it was reasonable to expect that the patient population subsequently treated under the HDE post-approval would encompass a broader range of clinical characteristics. The language of the FDA-approved HDE indication clearly allowed for this.

(3) The FDA-approved HDE indication for the Wingspan Stent System does not stipulate a time interval between (a) the time when a patient experiences a neurologic event, such as a stroke or TIA, attributed to intracranial atherosclerotic disease and (b) the time when the patient is treated with the Wingspan Stent System. It also does not restrict use of the Wingspan Stent System to patients who had a stroke, patients above a certain age, or patients who have stenoses in specific intracranial artery locations. Finally, the FDA-approved HDE indication does not specify the clinical parameters under which intracranial atherosclerotic disease is considered "refractory to medical therapy." These facts mean that a large group of patients who match the clinical characteristics profile of the SAMMPRIS trial subjects are eligible for treatment with this device under the FDA-approved HDE indication and will remain at risk as long as the device remains on the market.

(4) Despite the assertions made by Stryker spokesperson Tamara Cutler and FDA spokesperson Michelle Bolek, for several clinical and demographic parameters,

there was significant overlap between subjects in the SAMMPRIS trial and subjects in the Wingspan HDE safety study.

(5) In placing the SAMMPRIS trial results in appropriate context, the clinical characteristics profile of subjects in that trial should be compared not only to the profile of the small group of subjects enrolled in the small pre-market approval Wingspan HDE safety study, but also to that of patients treated with this device after approval. Patients who were enrolled in the post-market approval registry studies are representative of those patients treated with the Wingspan Stent System after approval, because they were considered eligible for treatment with this device under the FDA-approved HDE indication. There was significant overlap between the clinical characteristics profile of subjects in the SAMMPRIS trial and that of the several hundred patients who were considered eligible for treatment with the Wingspan Stent System under the FDA-approved HDE indication and enrolled in the two registry studies, the U.S. Wingspan Registry and NIH Wingspan Registry Study.

Finally, unlike the SAMMPRIS trial, the very small Wingspan HDE safety study provided no data on the relative safety and efficacy of treatment with the Wingspan Stent System in comparison to medical treatment only in any patient population. It is inconceivable that the FDA would have approved the HDE application for the Wingspan Stent System if the data from the SAMMPRIS trial had been submitted as part of the HDE application. In fact, it is likely that Boston Scientific Corp., the original manufacturer of the device, never would have sought such approval if such data had been available. The FDA's failure to immediately suspend approval of the HDE application for the Wingspan Stent System upon learning of the SAMMPRIS trial results, more than eight months after being informed that enrollment in the trial was terminated because of safety concerns regarding the risk of periprocedural stroke or death in the group undergoing treatment with the Wingspan Stent System,[44] represents a reckless disregard for patient safety.

Given the evidence of significant harm — a 2.5-fold increase in the risk of stroke or death in the first 30 days in those getting the Wingspan Stent — with no evidence of any benefit, there is no justification for any additional patients to be treated with this dangerous device. The only way that further use of the device can effectively and definitively be prevented is to immediately remove the device from the market, as it clearly cannot be said to provide reasonable assurance of safety. Rather, it guarantees an unreasonable risk of harm. To allow any further implantation of this device would be highly unethical as well as a violation of FDA laws and regulations.

III. Environmental Impact Statement

Nothing requested in this supplement to our original petition will have an impact on the environment.

IV. Certification

We certify that, to the best of our knowledge and belief, this petition supplement includes all information and views on which this petition supplement relies, and that it includes representative data and information known to the petitioners which are unfavorable to the petition.

Sincerely,

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Public Citizen's Health Research Group

Sarah Sorscher, J.D., M.P.H
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