

## OSCR MEDICAL DEVICE SUPPLY CHAIN OUTREACH QUESTIONS

### PUBLIC Disclosure Burden Statement

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Exhibit 1: Outreach to Medical Device Manufacturers  
Telephone script to be used at time of initial contact:

“Hello/Good Morning/Good Afternoon [insert name here],

My name is [insert name here] and I am from the Office of Supply Chain Resilience in the FDA’s Center for Devices and Radiological Health. Our Office’s mission is to strengthen public health supply chains by proactively monitoring, assessing, and communicating risks and vulnerabilities to prevent shortages of medical devices. Joining me today on this call are [insert name, role, and office].

An essential component of our work in OSCR is identifying supply chain risks and providing actionable information on those risks through close collaboration with industry and healthcare provider partners. One way we accomplish this is through outreach to stakeholders from across the medical device ecosystem, including medical device manufacturers, health care providers, professional and trade associations, etc. Any information shared with us that is trade secret or confidential information is treated as such, consistent with section 552(b) (4) of title 5, United States Code, section 1905 of title 18, United States Code, section 520(c) of 21 USC 360J(c), and other applicable laws.

The reason I/we am reaching out to you today is to discuss [insert company name here]’s perspective on the health of the supply chain for [insert device(s)] used in [insert procedure(s)], including current demand and availability. Specifically, we would appreciate your help with the following questions.

- Have you seen any changes in demand (e.g., last 3-6 months) for [insert device(s)] used in [insert procedure(s)]? If so,
  - From your perspective, what are the drivers of increased / decreased demand?
  - Can you quantify your current demand in contrast to current production output and in contrast to maximum capacity?
  - Which types of [insert device(s)] (e.g., [if applicable]) and sizes (e.g., [if applicable]) are impacted?
  - Can you please describe the allocation strategies you are using, if any?
- Can you please describe your mix of domestic and international manufacturing for these devices in the US market?
- Are you experiencing any issues with direct manufacturing (e.g. labor shortage, unscheduled maintenance, etc.) or with acquiring components or raw materials?

- Is there any additional information related to this topic that you think would be helpful for us to understand?

If you would like, I can forward this request to you via electronic mail.

Thank you for your collaboration and for taking the time to meet with me/us today.”

Exhibit 2: Outreach to Health Care Providers

Telephone script to be used at time of initial contact:

“Hello/Good Morning/Good Afternoon [insert name here],

My name is [insert name here] and I am from the Office of Supply Chain Resilience in the FDA’s Center for Devices and Radiological Health. Our Office’s mission is to strengthen public health supply chains by proactively monitoring, assessing, and communicating risks and vulnerabilities to prevent shortages of medical devices. Joining me today on this call are [insert name, role, and office].

An essential component of our work in OSCR is identifying supply chain risks and providing actionable information on those risks through close collaboration with industry and healthcare provider partners. One way we accomplish this is through outreach to stakeholders from across the medical device ecosystem, including medical device manufacturers, health care providers, professional and trade associations, etc. Any information shared with us that is trade secret or confidential information is treated as such, consistent with section 552(b) (4) of title 5, United States Code, section 1905 of title 18, United States Code, section 520(c) of 21 USC 360J(c), and other applicable laws.

The reason I/we am reaching out to you today is to discuss [insert health care facility name here]’s perspective on the availability of [insert device(s)] and to better understand their availability and use in clinical practice. Specifically, we would appreciate your help with the following questions.

- Have you experienced any recent (e.g., last 3-6 months) challenges with availability of [insert device(s)]? If so,
  - Are there specific devices from specific manufacturers or distributors on allocation and at what level?
  - Can you please describe those challenges and any communication or guidance you have received from your vendor(s) or the manufacturer?
  - Can you please tell us about if/how you have needed to adapt approaches to patient care or [insert device(s)] utilization as a result of challenges with availability?
  - Can you please describe how those availability challenges have impacted patient outcomes, if at all?
- Is there any additional information related to this topic that you think would be helpful for us to understand?

If you would like, I can forward this request to you via electronic mail.

Thank you for your collaboration and for taking the time to meet with me/us today.”

Exhibit 3: Outreach to Professional/Trade Associations  
Telephone script to be used at time of initial contact:

“Hello/Good Morning/Good Afternoon [insert name here],

My name is [insert name here] and I am from the Office of Supply Chain Resilience in the FDA’s Center for Devices and Radiological Health. Our Office’s mission is to strengthen public health supply chains by proactively monitoring, assessing, and communicating risks and vulnerabilities to prevent shortages of medical devices. Joining me today on this call are [insert name, role, and office].

An essential component of our work in OSCR is identifying supply chain risks and providing actionable information on those risks through close collaboration with industry and healthcare provider partners. One way we accomplish this is through outreach to stakeholders from across the medical device ecosystem, including medical device manufacturers, health care providers, professional and trade associations, etc. Any information shared with us that is trade secret or confidential information is treated as such, consistent with section 552(b) (4) of title 5, United States Code, section 1905 of title 18, United States Code, section 520(c) of 21 USC 360J(c), and other applicable laws.

The reason I/we am reaching out to you today is to discuss [insert organization name here]’s perspective on the availability of [insert device(s)] and to better understand their availability and use in clinical practice. Specifically, we would appreciate your help with the following questions.

- Are you aware of your members experiencing recent (e.g., last 3-6 months) challenges with availability of [insert device(s)]? If so,
  - Can you please describe those challenges and any communication or guidance you or your members have received from the vendor(s) or the manufacturer?
  - Can you please describe any communications and/or guidance your organization has provided to members as a result of challenges with availability of [insert device(s)]?
  - Can you please tell us about if/how your members have needed to adapt approaches to patient care or [insert device(s)] utilization as a result of challenges with availability?
  - Can you please describe how those availability challenges have impacted patient outcomes, if at all?
- Is there any additional information related to this topic that you think would be helpful for us to understand?

If you would like, I can forward this request to you via electronic mail.

Thank you for your collaboration and for taking the time to meet with me/us today.”

Exhibit 4: Outreach to Purchasing Organizations/Distributors  
Telephone script to be used at time of initial contact:

“Hello/Good Morning/Good Afternoon [insert name here],

My name is [insert name here] and I am from the Office of Supply Chain Resilience in the FDA’s Center for Devices and Radiological Health. Our Office’s mission is to strengthen public health supply chains by proactively monitoring, assessing, and communicating risks and vulnerabilities to prevent shortages of medical devices. Joining me today on this call are [insert name, role, and office].

An essential component of our work in OSCR is identifying supply chain risks and providing actionable information on those risks through close collaboration with industry and healthcare provider partners. One way we accomplish this is through outreach to stakeholders from across the medical device ecosystem, including medical device manufacturers, health care providers, professional and trade associations, etc. Any information shared with us that is trade secret or confidential information is treated as such, consistent with section 552(b)(4) of title 5, United States Code, section 1905 of title 18, United States Code, section 520(c) of 21 USC 360J(c), and other applicable laws.

The reason I/we am reaching out to you today is to discuss [insert organization name here]'s perspective on the health of the supply chain for [insert device(s)] used in [insert procedure(s)], including current demand and availability. Specifically, we would appreciate your help with the following questions.

- Are you aware of recent (e.g., last 3-6 months) challenges with availability of [insert device(s)] to meet customer demand? If so,
  - Can you please describe those challenges and any communication or guidance you or your members/customers have received from the manufacturer?
  - Can you please describe any communications and/or guidance your organization has provided to your members/customers as a result of challenges with availability of [insert device(s)]?
  - Can you please tell us about what you are hearing from members/customers as a result of challenges with availability of these devices?
  - Are any of these [insert devices] on distribution allocation and at what level? If so, when do you anticipate distribution allocations to end?
- Is there any additional information related to this topic that you think would be helpful for us to understand?

If you would like, I can forward this request to you via electronic mail.

Thank you for your collaboration and for taking the time to meet with me/us today.”