



Impact of the IRA: a survey

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BioCentury survey on the impact of the IRA

The Inflation Reduction Act, signed into law on Aug. 16, 2022, ushers in a new series of considerations for biopharma companies as they build and develop their pipelines. The act creates a framework for regulating the prices Medicare pays for drugs and restructures the Part D benefit. These changes will reshape the commercial landscape for drugs and biologics in the U.S., including for sales outside Medicare.

For the first time, the IRA introduces price negotiations – seen by the industry as “price setting” – where Medicare can regulate the prices it pays for certain drugs. How HHS will exercise its authority isn’t yet clear, and are part of the uncertainty companies are navigating.

Though the policies are baked into U.S. law, they will impact biopharmas globally, meaning companies and biotech investors in all countries need to understand the new dynamics of drug pricing and adapt their strategies.

BioCentury’s survey, supported by BIO, focuses on how company executives and investors are thinking about:

- Pipeline prioritization
- Modality choice
- Orphan drug indications
- Partnering strategies



Change is coming: pipeline makeovers in the works

Key survey findings: Overall impact and pipeline strategies

- **Even before the IRA's provisions have come into effect, it is having a broad impact on the biopharma industry**

Companies large and small are anticipating change to their business models, with more than one third categorizing the impact as “major” or even existential. On the whole, the level of concern tracks with revenue and company size – the higher-revenue and larger companies are the most concerned. A fair proportion of small and midsize companies are still digesting the implications of the new law, and there are a few holdouts in this class who don't – yet? – see relevance to their businesses.

- **Competitive landscapes will inevitably change, as companies are upending their pipeline and commercialization strategies**

Companies are preparing to ditch the longstanding approach of seeking proof of concept in a small indication, then expanding a drug's label to larger indications. A majority are considering going straight to a drug's largest target population, and recalibrating the calculus for adding subsequent indications, meaning the “pipeline in a product” strategy may no longer make sense. At the same time, almost half are considering pursuing smaller indications outside of the U.S., which could shift the geographic distribution of sales and revenues.



Digesting the IRA and recalculating risk

Key survey findings: indications, modalities and business development

- **Expect pivotal changes in orphan drug strategies and modality choice**

The exemption from price-setting for drugs with only one orphan indication is sending companies in different directions. About one third of companies are prioritizing rare over common diseases, while an equal number are limiting their programs to a single orphan indication per drug. At the same time, a majority of respondents are planning or considering a shift to biologics rather than small molecules, putting the IRA head-to-head with science and CMC for optimizing molecule choice.

- **The IRA may accentuate the buyers' market for partnering and M&A**

Companies and investors don't expect to change their partnering and deals strategy much, though about one third believe they'll be pushed to partner earlier. But it's clear that decreased valuations of products and companies are going to lead to worse terms for sellers, who are expecting lower upfront payments, milestones and takeout premiums. And companies will need to communicate their strategies to investors and partners for how they plan to manage or avoid the impacts of the IRA.



Survey Details

- The survey ran from Jan. 31 to Feb. 13, 2023
- Conducted and analyzed by BioCentury editorial staff, with design input from BIO
- BioCentury subscribers, BIO CEO & Investor Conference attendees and BioCentury social media subscribers invited to answer
- 79 respondents:
 - 69 from biopharma companies
 - 10 from venture capital or other investment organizations
 - 59 in U.S., 16 in Europe, 3 in Canada, 1 in Asia



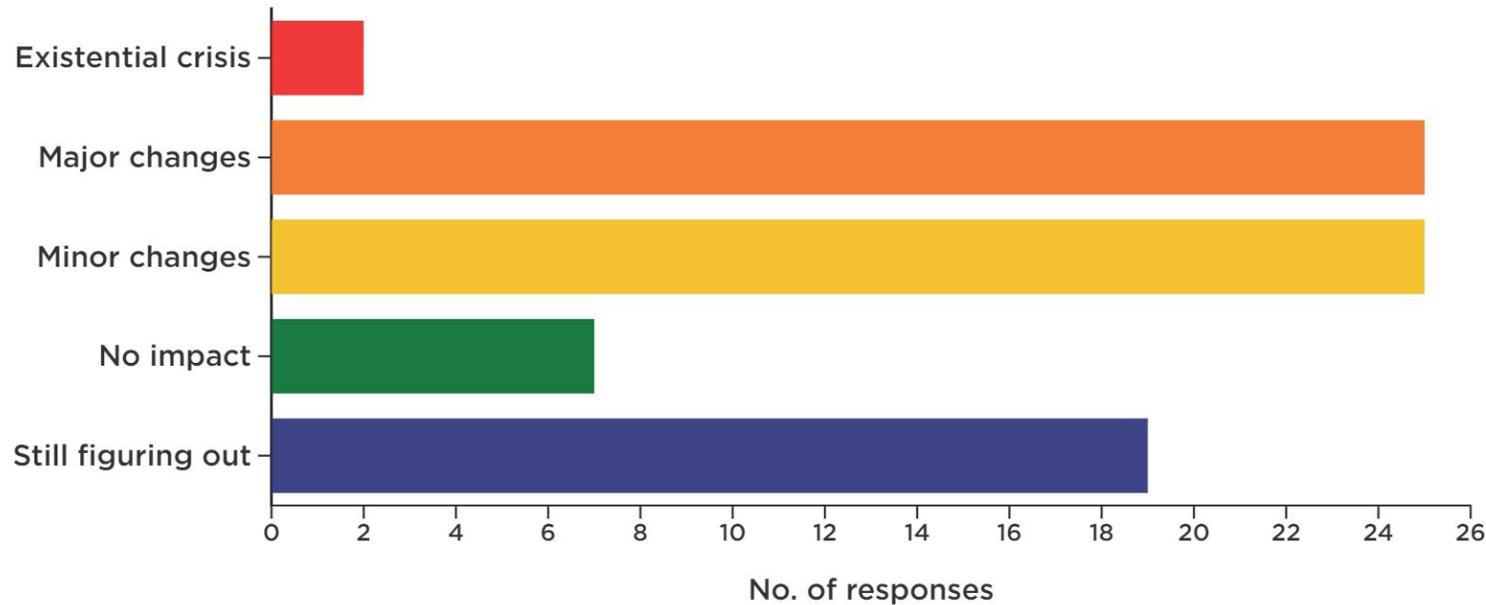
Overall impact of IRA



The IRA's footprint is deep and broad

Two thirds of respondents anticipate changes to their business

Impact of IRA on your business



- One third (34%) of biotechs and investors expect the IRA to create major changes or an existential crisis for their businesses
- Another third (32%) expect minor changes
- One quarter (24%) are still figuring it out
- Only 9% don't expect any impact

Source: BioCentury Inflation Reduction Act Survey • n=78

How big an impact will the IRA have on your company or your portfolio companies?

N=78



Companies with revenues are the most concerned

Those on the fence tend to be low or pre-revenue

Breakdown of impact by revenue



- Almost all respondents with revenues over \$100M – including those over \$1B – see major or minor changes ahead
- Companies with less or no revenue are more likely to be still figuring it out – about one third of each group
- The only companies expecting no impact are those that do not yet have marketed products

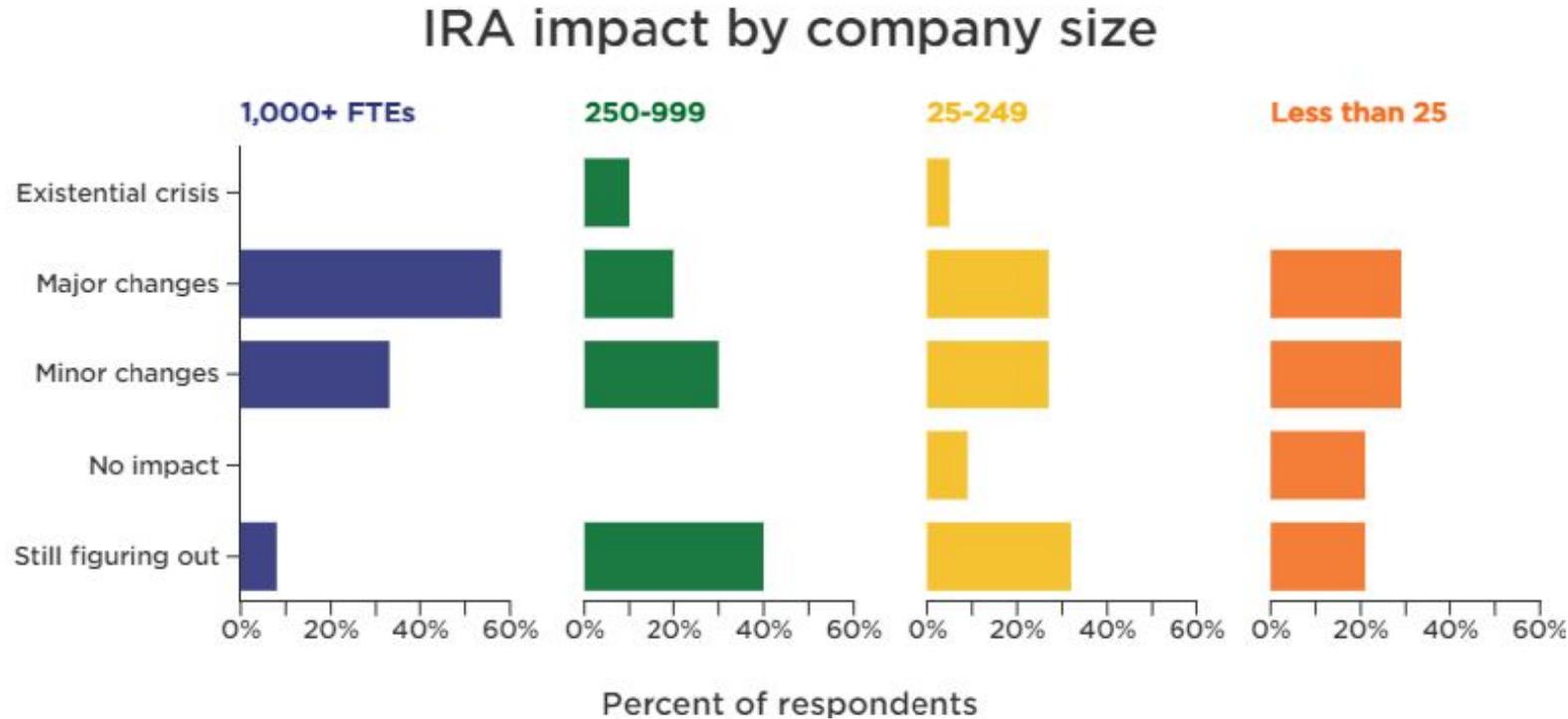
How big an impact will the IRA have on your company?

N=68 (biopharmas only)



The smaller the company, the less relevant they see IRA

But SMEs *ARE* bracing for impact



- The few companies that don't expect an impact are in the small or very small categories (<250 FTEs)
- Even among this <250 group, the majority (55-60%) expect major or minor changes
- While 40% of midsize companies (250-999 FTEs) are still figuring it out, the larger companies are most commonly (58%) expecting major changes

How big an impact will the IRA have on your company?

N=68 (biopharmas only)



What effects of the IRA do you expect for your company?

Downsides... (from write-in responses)

Limits potential for price increases, which will force evaluation of higher launch price. Limit interest in seeking additional indications for therapies with orphan designation – will choose instead to seek additional indications outside the U.S. and/or seek compendia in U.S. only

Drive choice to invest in non-medicare indications

Lower valuation, need to prioritize indications and decide not to pursue additional orphan indications

IRA is particularly devastating in the neuroscience field, where timelines for development are already longer, success metrics lower and reimbursements not at all assured



Not everyone sees the empty half of the glass

Though a minority, some responses reflected optimism or neutrality

I believe the IRA will have a positive effect on our company. We are developing several products (Phase II ready) for large unmet needs with the goal of democratizing healthcare

The IRA will have no effect on the funding and innovation of new products – people always scream and yell at legislation like this, in the end, we will continue to develop new medicines and if they are truly medically useful and innovative, the dollars will flow

Its impact has been overstated



Pipeline decisions



IRA effect on pipeline strategy

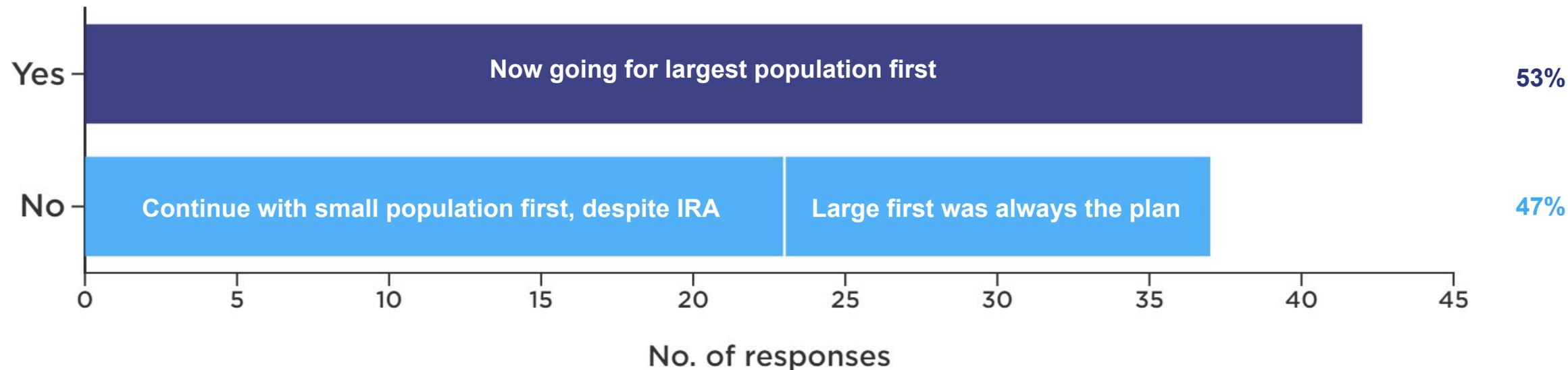
- Under the IRA, products will be subject to price setting 9 years (NDAs) or 13 years (BLAs) after approval.
- As a result, companies may be incentivized to seek approval in the broadest possible indication first to maximize total sales in the time before they become subject to price-setting
- It may also discourage conducting trials to add new indications late in the window before price-setting
- Orphan drugs are exempt from price-setting, but only if approved for a single orphan indication. This means approval of another indication can make the medicine subject to price negotiation
- The survey asked how these changes might affect respondents' pipeline strategies, including their selection of indications and modalities



Starting in small indications will fall out of favor

More than half respondents will go to market first in largest population

Will market size change your plans?



Do you expect the IRA will affect your prioritization of indications based on market size?

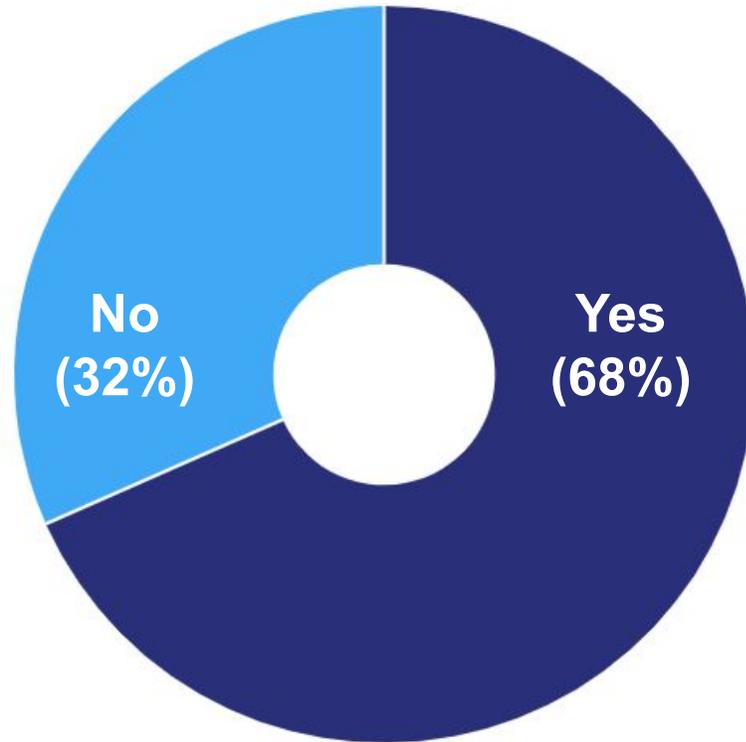
N=79



Will “pipeline-in-a-product” become a thing of the past?

Most are recalibrating the calculus for adding on indications

Rethinking next indications?



- More than two thirds of respondents say they will rethink how they go about adding indications for approved drugs
- Parallel development will likely be the best way to target multiple indications in the allotted time window
- For others, it may mean building a pipeline of different indications from a single product is no longer commercially viable

Does the IRA change your thinking about developing additional indications for approved drugs?

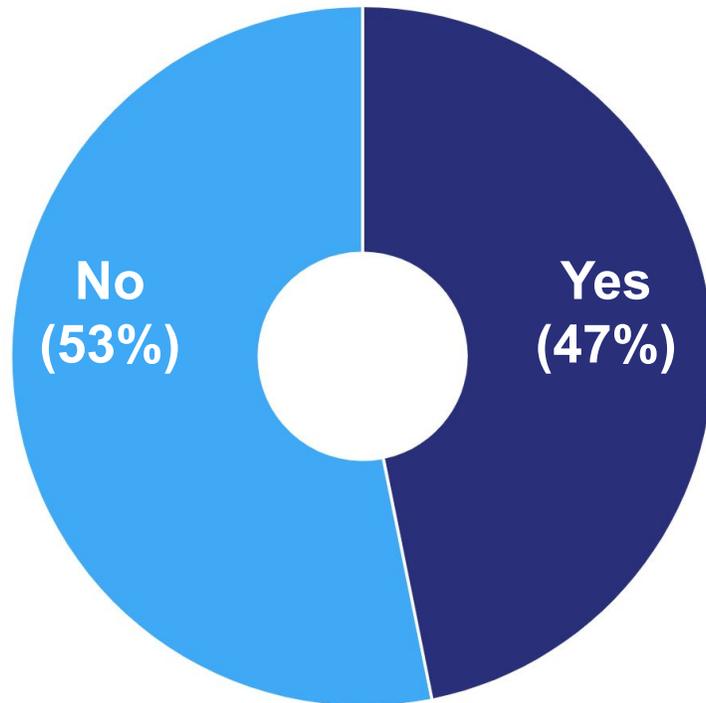
N=79



Going overseas first could work better

Almost half are considering a new geographical strategy

**Aiming for smaller indications abroad,
keeping large ones stateside?**



- Global commercialization strategies will undergo major changes as companies consider first commercializing their products in smaller indications outside of the U.S.
- Respondents who answered “yes” did not skew to any geographic location

Are you considering seeking approval in smaller indications outside the U.S. while waiting to seek approval in a larger indication in the U.S.?

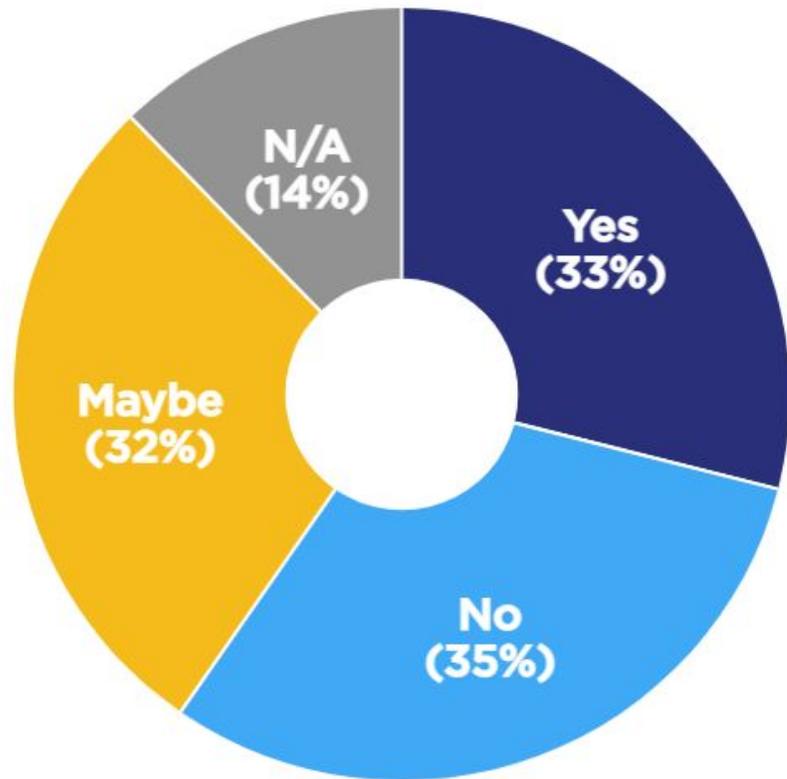
N=79



The landscape will change for orphan indications

A majority are planning or considering changes to their orphan drug strategy

Changing orphan strategy?



- More than one third are changing their strategy on orphan indications because of provisions in the IRA, another third are considering doing so
- Reasons differ (see next slide), but there is no segregation of responses by company size, revenue or geography
- N/A refers to companies that are not developing drugs for the Medicare population

Will your strategy change for orphan indications?

N=72



The landscape will change for orphan indications

Breaking down the rationales

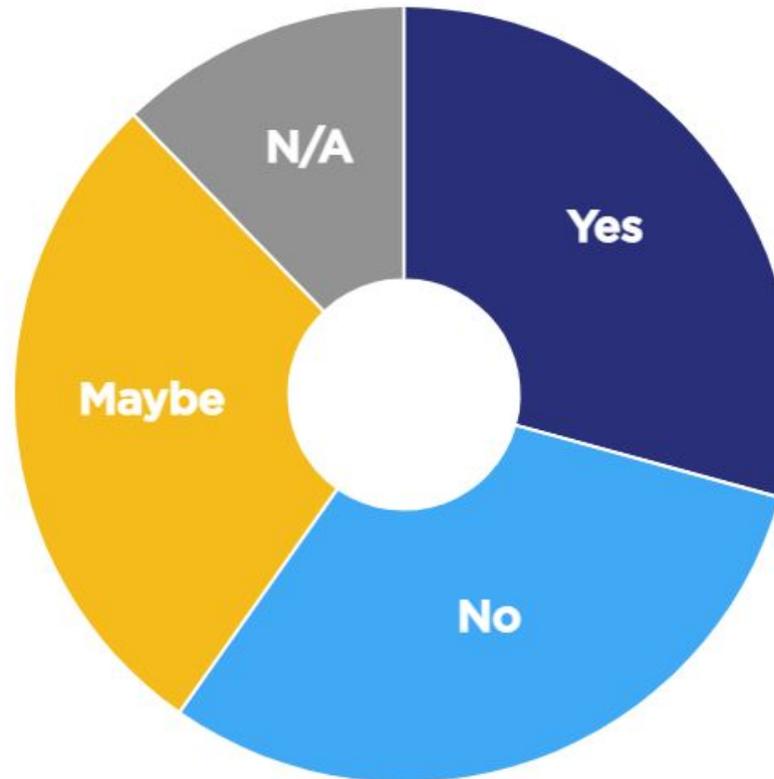
Not applicable:

- Not developing drugs for Medicare population

Maybe:

- Considering change to orphan strategy

Changing orphan strategy?



Yes, we will now:

- Prioritize orphan diseases over common
- Pursue one orphan indication instead of multiple
- Develop distinct products for the indications

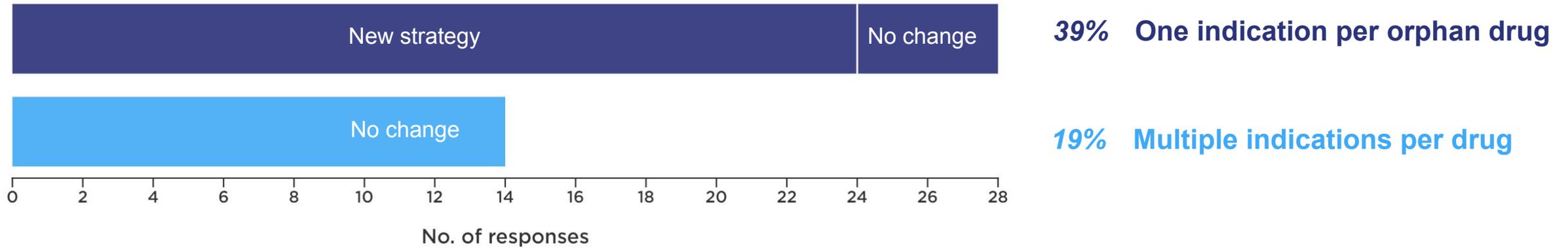
No change:

- Still pursuing multiple indications per drug
- One indication was always the plan



One orphan indication per drug to become the default

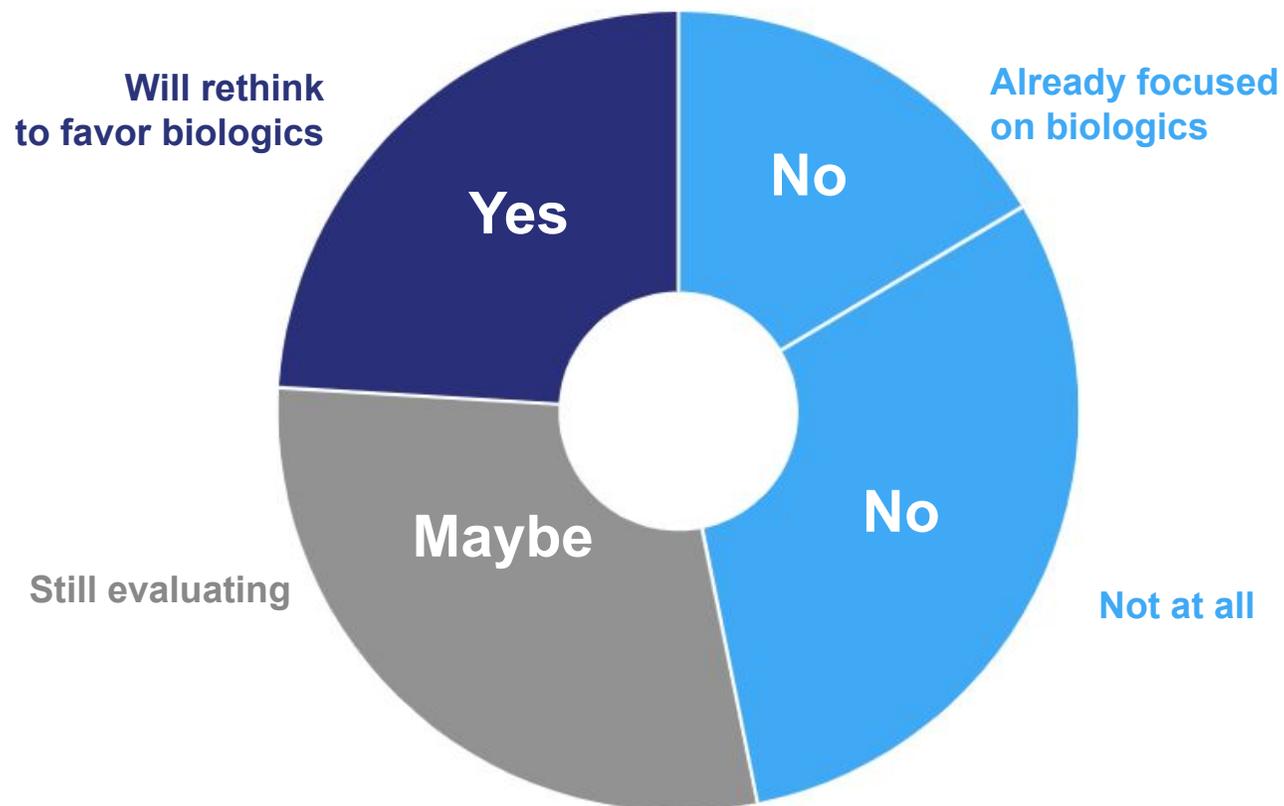
Patients and companies may not get the most value possible from each drug



Expect a shift from small molecules to biologics

A move to biologics is in the plans or under review for more than half respondents

Changing course on modality?



- Nearly one quarter (24%) are planning to prioritize their pipelines towards biologics. All but one of these are U.S.-based companies
- Another 29% are weighing whether to shift to biologics
- A sizeable minority (38%) have no plans to rethink their pipelines, with the balance (16%) already focused in those modalities

Is the IRA causing you to rethink pipeline prioritization or portfolio investments based on modality?

N=79



How companies are weighing their decisions

We will very likely stop pursuing indication expansion for small molecule therapies. This will raise the bar on the molecules that we advance, leaving some promising compounds deprioritized because of risk-value equation

Since we are targeting ultra rare conditions, having a degraded access to the U.S. market often makes the business case no longer work for these diseases thereby we will refrain ourselves from developing our drugs in some indications

The 9 vs 13 gap will create perverse incentives and create greater risk that certain patient populations will not be addressed

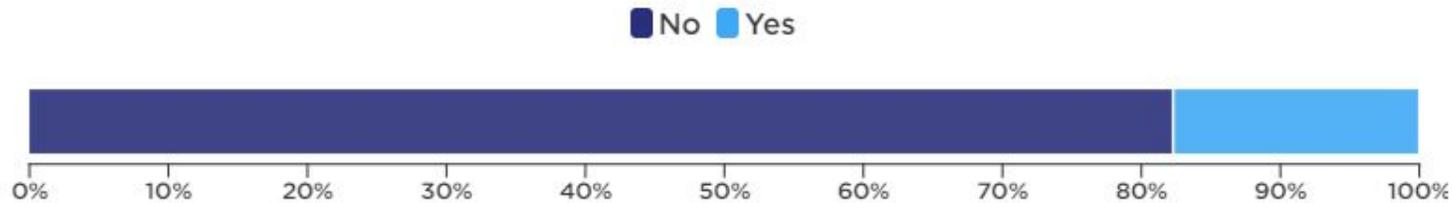


Business development



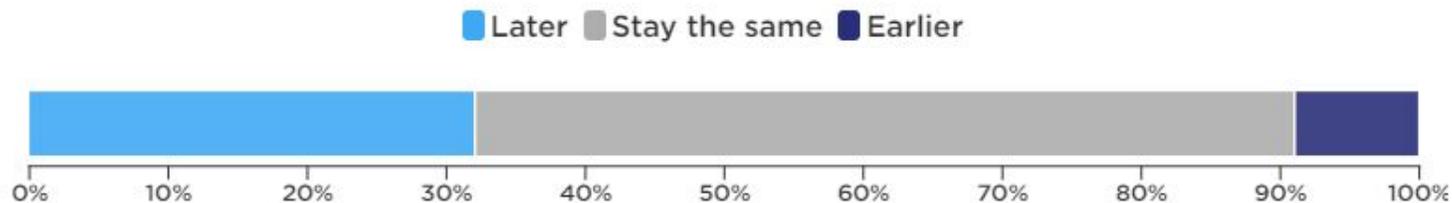
IRA won't change the partnering trajectory

Changes to your BD strategy?



- Most respondents don't see an immediate change to their BD strategy, though a sizeable minority (32%) think the IRA will push companies to partner their products later in development

Change deal timing in stage of development?



*Do you anticipate that the IRA might affect your BD and deal-making strategy?
Will the IRA change the stage of development at which deals are signed?*

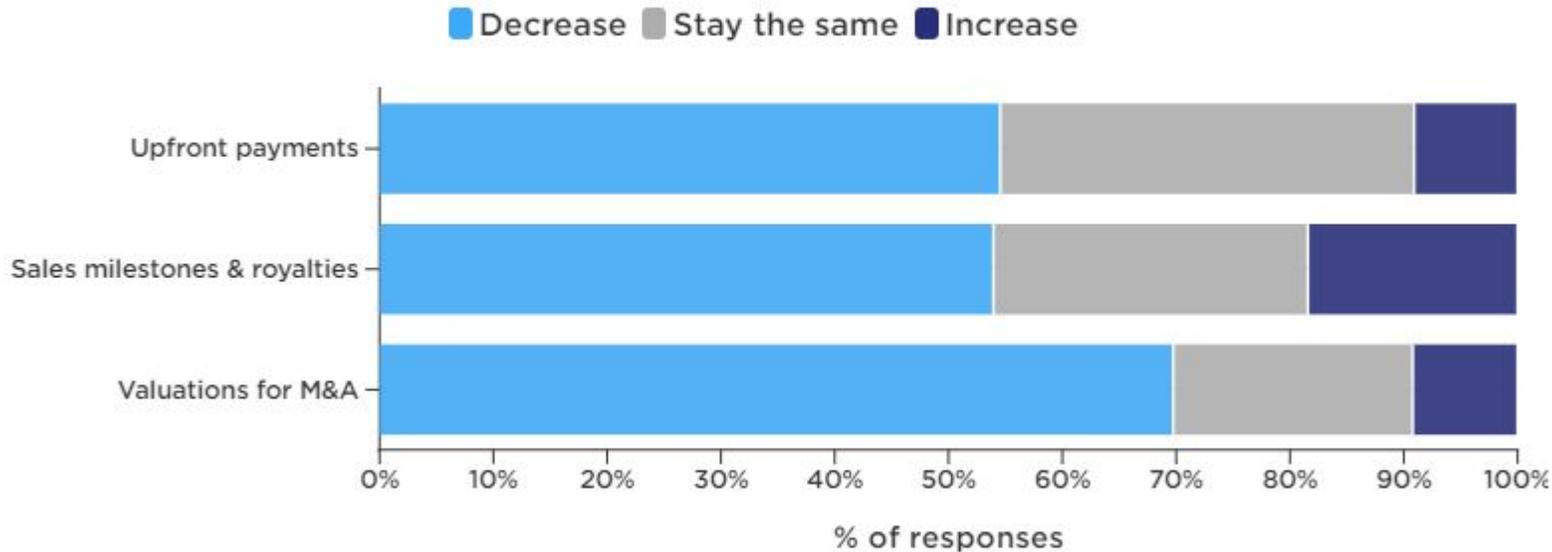
N=79, 78



But broad pessimism on deal valuations

IRA is likely to curb revenues from partnering and M&A

Expectations for deal terms



- A majority of respondents believe that deal terms will become worse for licensees and sellers
- 54% see decreases in upfront payments as well as sales milestones and royalties, with 70% seeing lower M&A valuations

Capital concerns

Anticipated effects on fundraising and partnering

I think it will be difficult to raise capital unless we can articulate how we aren't impacted by the IRA. That may include focusing on indications where Medicare isn't the predominant payor (i.e., away from oncology, or oncology indications more common amongst those under 65)

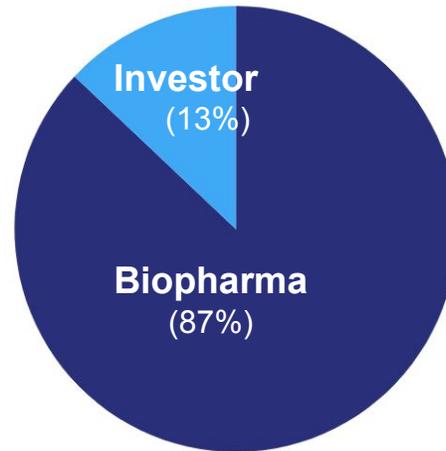
It is chilling. We have been developing a small molecule drug and expect our ability to partner this drug to have gone down significantly because of the IRA

Lower return on investment, which will affect investment decisions

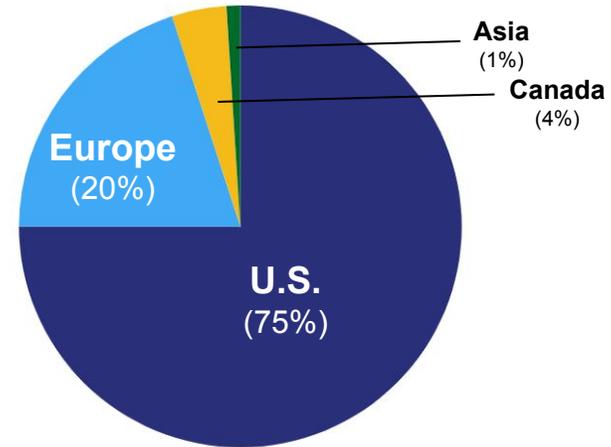


Respondent demographics

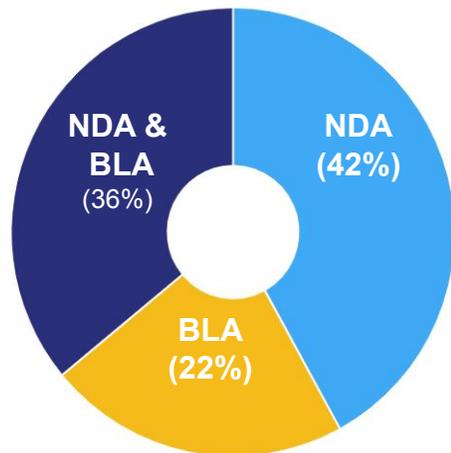
Company vs VC



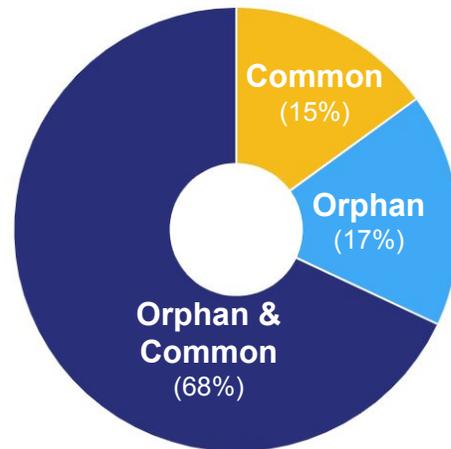
Location of HQ



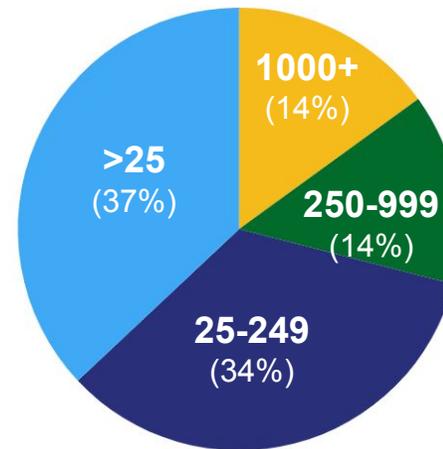
Pipeline focus



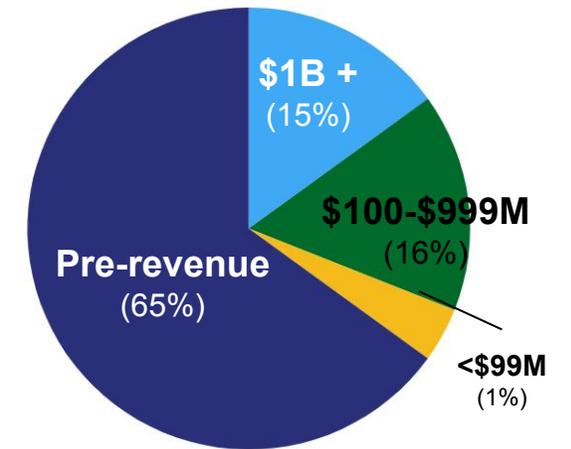
Orphan vs Common



Company size (FTE)



Product revenues



BioCentury Coverage on the Inflation Reduction Act

Articles:

Navigating the Inflation Reduction Act [[Article](#)]

The IRA's single-orphan conundrum [[Article](#)]

IRA: how low will they go? [[Article](#)]

IRA discourages multiple orphan indications [[Article](#)]

Biotech investors bracing for Inflation Reduction Act's impacts [[Article](#)]

Multimedia:

[Podcast](#): IRA Essentials

[Webcast](#): Narasimhan: Inflation Reduction Act forcing pharmas to rethink pipelines

[Webcast](#): Get used to markets with no nuance, says Blackstone's Kiran Reddy



Join us for more discussion

Complimentary webinar — Navigating the IRA: What biopharmas need to know

BioCentury and Putnam bring together a panel of industry experts for a webinar to learn how the IRA will impact drug developers everywhere.

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